UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	March 23, 2018
Sherr-Una Booker, an individual,	
Plaintiff,	
v.	CV-16-00474-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 7 A.M. SESSION

(Pages 1323 - 1449)

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I N D E X

EXAMINATION

EXHIBITS

10:01:31

P R O C E E D I N G S

(Proceedings resumed in open court outside the presence of the jury.)

08:31:11

THE COURT: Please be seated.

Morning, everybody.

EVERYBODY: Morning, Your Honor.

THE COURT: Long week, but one more day for this week.

08:31:29

Plaintiff's counsel, do you have matters that you would like to raise this morning before we start?

MS. REED ZAIC: Yes, Your Honor.

MS. MATARAZZO: Good morning, Your Honor. We just have one exhibit issue which we're trying to work out with

08:31:49

defense counsel. We got the exhibits late yesterday so we haven't had time to work through it fully. But I just wanted to alert the Court that there are certain documents that we don't object to most of the content of and -- but we have an objection to some of the content in the document.

08:32:06

So, for example, there's a submission to the FDA here, which is defense Exhibit 5325. We don't object to the majority of the content, but within the -- within this submission to the FDA there's a medical journal article. So

08:32:24

we don't want that, obviously, to go back to the jury or be published. And then there's also call notes in here,

08:32:28 conference call notes, which are hearsay.

So we're trying to work out a procedure where the jury's able to get the majority of the document but not all of the document, and that's going to be an issue that will 08:32:41 probably come up, and I'm not sure quite how the Court wants to handle it, whether to admit it or not while we're figuring out if we can work out a way to get most of the document in, but not all of it, and whether or not defense counsel agrees with us.

08:32:56 THE COURT: Are these exhibits to be used today?

MS. MATARAZZO: I believe so. They're on their exhibit list for their witnesses today.

THE COURT: Defense counsel?

MR. NORTH: We're in the process of meeting and 08:33:05 conferring. I don't believe these will be used until after lunch today, so perhaps we can talk at the break and -- or even in a few minutes and address this at the noon hour if need be.

THE COURT: Do you have any intention, Mr. North, of 08:33:21 displaying to the jury the portions the plaintiffs are concerned about?

MR. NORTH: No. This document's not going on with the first witness today.

THE COURT: No, I mean, but even if you get to it 08:33:31 this afternoon, do you intend to put up on the jury screen

08:33:35 portions of the exhibit that they're objecting to?

MR. NORTH: No.

THE COURT: Well, it seems to me what we could do in response to the question is we could, to keep the case moving,

08:33:44 if you haven't had time to work it out, we could admit the document subject to the objections plaintiff wants to make to specific portions. It wouldn't be any prejudice if those aren't shown to the jury or asked about of the witness. And if you can't work it out over the weekend, then I can hear you

08:34:02 at some point and decide what portion is to be excised.

MS. MATARAZZO: That's acceptable to us, Your Honor.

THE COURT: And I would say we ought to do that going forward with any exhibit where you're under discussion. But if it comes to a point where you're going to use something the

08:34:18 plaintiffs are objecting to, then obviously you ought to bring that to me so I can make a decision. But I think you ought to have as much time as possible to work this out.

MR. NORTH: Certainly.

THE COURT: So I think for today we'll be okay on

08:34:28 that.

MS. MATARAZZO: Thank you, Your Honor.

THE COURT: Does that sound right?

MS. MATARAZZO: Yes.

THE COURT: Plaintiffs have other matters,

08:34:33 Mr. O'Connor?

08:34:36 The mic.

MR. O'CONNOR: Excuse me.

The issue that we raised at sidebar while Sheri Booker was testifying, I think you said that you were
08:34:45 going to take it under advisement whether we can call her back, and then we need to make a decision whether we're going to call her back.

The only reason I'm raising that now is that our case is about to end, and will we be precluded from reopening for
08:34:58 that point, if necessary?

THE COURT: Well, here was my thought on that, Mr. O'Connor. It seems to me that the concerns that you expressed may be resolved by an instruction, and you're going to propose one. Or at least I may think they're resolved.

08:35:15 At this point I don't want to open the door to issues about what she could afford or what she had insurance for, because I think that does open a broader issue. So I think what we ought to do is have you submit the instruction. If I decide, after we've discussed that and I've made a decision,
08:35:30 that you should be allowed to go into her inability to pay, you can do that in the rebuttal case.

So I guess my point is it seems to me you can close today without prejudice to your ability later to raise the issues we talked about at sidebar if I let you do that and if
08:35:46 they're not resolved through the instructions.

08:35:49 Does that make sense?

MR. O'CONNOR: Yeah. Yes, that makes sense and I understand your point. From our perspective, of course, they heard the testimony that shouldn't have come in. But I see
08:36:02 that -- I think we need to consider can we be satisfied that a limiting instruction, from our perspective, will work, or do we need to raise it with and you will you allow us to bring our client back, if we think that's another -- in addition to limiting instruction, that's another way to cure what happened
08:36:24 yesterday --

THE COURT: And my point is we are not closing the door on that now.

MR. O'CONNOR: All right.

THE COURT: By your resting, you're not closing the
08:36:30 door on the possibility of you recalling her or putting her on in your rebuttal case on that issue if I decide you're entitled to do it.

MR. O'CONNOR: Thank you.

THE COURT: Okay.

08:36:38 Other matters for plaintiff?

MR. LOPEZ: Yes, Your Honor. One other issue.

The defense is about to put on their case. We've seen their exhibits. In fact, we've already seen some testimony. This goes to the issue of FDA action, inaction,
08:36:52 failure to do things, not doing things.

08:36:58 CFR 21, Section 2 -- 20.1 is testimony by Food and Drug Administration Employee. This is the section which precludes us from subpoenaing and taking the deposition of FDA employees. I think it's important for the jury to understand, 08:37:18 because they're going to wonder why is someone from the FDA not here to testify. And I don't know what's coming in, I don't know what's going to be allowed to come in in the defense case with respect to their communications with FDA, but I would like the jury to know that the FDA cannot be 08:37:36 subpoenaed, we cannot get the other side of the story. We cannot cross-examine people at FDA that were involved in any of these transactions. And I'm not sure how to do that yet, but I think they ought to know that.

And if you want a cite, we can even read from this 08:37:50 code section. I mean, this basically -- I mean, this is the law.

But the jury -- I don't care how they get to know, but they need to know that the reason FDA is not testifying, we don't have counter-testimony from FDA is because we're 08:38:05 precluded from getting it.

THE COURT: Are you suggesting, Mr. Lopez, that I should do something about that now? That I should instruct them now?

MR. LOPEZ: No, because the evidence hasn't come in 08:38:14 yet. But should it come in, I think that we're probably going

08:38:17 to want to discuss this again. I just wanted to give the Court --

THE COURT: Okay. You've given me that heads-up and you can raise it again if you need to.

08:38:24 MR. LOPEZ: Thank you.

THE COURT: Anything else?

Mr. Johnson?

MR. JOHNSON: Judge, we've been provided with a PowerPoint presentation that we anticipate the defense will

08:38:37 use with the first witness this morning, and we have an objection to it. The punchline is that the PowerPoint itself is hearsay. It summarizes many, many hearsay documents that are not in evidence. It is also a summary of this witness's report that was given in this case, the Rule 26 report, which

08:38:56 we all know is not admissible in evidence.

So we believe this PowerPoint should not and cannot be used basically on hearsay grounds.

THE COURT: How are you intending to use it, Mr. North?

08:39:08 MR. NORTH: Only as demonstrative exhibits. These have been prepared by our expert, Your Honor, to sort of summarize the key points, bullet points of her opinion, which she will then talk about. But they're purely demonstrative, and there are only like five or six slides here.

08:39:21 THE COURT: Could you give me a copy.

08:39:24 MR. NORTH: Okay.

Your Honor, I only have one copy, so I'm taking my notes off of them here.

THE COURT: All right.

08:39:41 Do you have a extra copy, Mr. Johnson?

MR. JOHNSON: I don't, Your Honor.

And, Judge, I might add that on one of these slides there's a bullet point that I think violates the Court's order on plaintiff's Motion in Limine Number 1.

08:40:02 THE COURT: Hold on until I look at these.

Okay. Give me the specific objections you have, Mr. Johnson.

MR. JOHNSON: Judge, for example, on page 1 with the regulatory history --

08:41:25 THE COURT: Page 1 doesn't have regulatory history on it.

MR. JOHNSON: Well, I'm looking at some cover page entitled 2004-2005 Recovery filter --

THE COURT: That's the second page on the list I'm

08:41:38 given.

MR. JOHNSON: Okay. All right.

They, in essence, summarize in some of these bullet points what was discussed by and between Bard and the FDA. None of these documents are in evidence. It's a summary of

08:41:56 hearsay information, and it's an attempt to publish to this

jury hearsay information, hearsay documents that are not in evidence, so we object --

THE COURT: Give me a specific example from the slide of what you think is hearsay.

MR. JOHNSON: January 27, FDA and Bard discuss complication rates.

THE COURT: Well, the communication, that is what was said, isn't here. So the hearsay isn't here; right? The actual back and forth between them.

MR. JOHNSON: Well, then there would be a 403 objection that the inference here is that the FDA approved the actions of Bard going forward. So it would be misleading and confusing to the jury.

They want to place an inference before this jury that they were completely up-front with the FDA, and the FDA blessed the actions of Bard going forward.

THE COURT: They do. I mean, that's going to be a big part of their defense, is that they presented this to the FDA and they got clearance.

I think I ruled on that, that they could do that. Now, I know that that's not unlimited. But -- let's take these one at a time. I want to deal with your hearsay issue first. I'm not seeing January 27th as including any hearsay.

MR. JOHNSON: Well, the document itself is hearsay, Your Honor. I mean, this witness --

08:43:20 THE COURT: But it's not coming into evidence. Right? So the problem is -- or the question is should it be allowed to be used as demonstrative? And obviously a demonstrative that conveys hearsay shouldn't be used. So I'm
08:43:34 trying to understand where the hearsay is in the document.

MR. JOHNSON: Judge, this is basically this witness's report that is never going to be admissible in evidence in this Court. It will never be published to this jury. And this is a backdoor attempt to publish to this jury this
08:43:52 witness's Rule 26 report.

She can talk all day long about her opinions in this case. She can give the basis for her opinions. But I believe it's inappropriate for this witness to back door her report. We can't do it and they can't do it.

08:44:10 THE COURT: Mr. North, I assume you agree that this witness's report would be hearsay and inadmissible.

MR. NORTH: Absolutely, Your Honor.

THE COURT: As would be a PowerPoint that restated everything in her report and was displayed to the jury.

08:44:25 MR. NORTH: Right. In detail. Absolutely.

THE COURT: Why isn't this a short version of that? Namely, you've taken the high points from a report and you want to have the jury read them.

MR. NORTH: First of all, it's not a verbatim
08:44:41 statement of her report, it's merely a summary of the

highlights that she's going to be there talking about. It's not going in in evidence. It's just a way to visually -- as demonstrative evidence. I don't think it's much different than the ten-minute animation we saw with regard to the surgical procedure. It's just demonstrating for the jury the highlights of what she's saying.

THE COURT: Hold on just a minute.

Well, as you know, there's no rule of evidence on demonstrative exhibits. Rule 901 applies in that any information conveyed in a demonstrative exhibit has to meet the authenticity requirements that anything shown to the jury does, which is usually by the witness saying it is an accurate depiction of.

The question for whether a demonstrative exhibit can be used is whether it would be helpful to the jury in understanding the witness's testimony. So with that being the sort of contours for a demonstrative exhibit, explain to me, if you would, Mr. Johnson, why you think this is impermissible. I understand your point that it's essentially showing the jury the witness's report, which is inadmissible. But these aren't verbatim, they're sort of timelines which arguably would help the jury understand the timeline that the witness is laying out.

MR. JOHNSON: I hope this answers your question, but my view of demonstrative evidence has always been that it has

08:47:05 to be based on admissible evidence. For example, when we played the animation of the surgery, that was based on an operative report that was in evidence.

THE COURT: Well, I agree with that. But are you
08:47:18 saying that she could not testify that based on her examination of the record and her preparation for trial, that on January 27th the FDA and Bard discussed complication rates? I mean, if she can say that, it's admissible evidence, so this part of the slide is based on admissible evidence.

08:47:39 MR. JOHNSON: But a summary of that discussion, I think, is still hearsay. She can say they had a meeting.

THE COURT: Right.

MR. JOHNSON: Okay? But then to say they discussed this, there's hearsay by whoever on Bard's side discussed that
08:47:54 subject matter, there's hearsay from the FDA, and there's a double hearsay issue as well.

THE COURT: Well, I think this is an important point, so let me keep pressing you on this.

Okay. Let's take that example. On January 27th the
08:48:07 FDA and Bard discussed complication rates. What communication from Bard or the FDA on that date is being offered in evidence for the truth of the matter asserted such that it is hearsay?

MR. JOHNSON: That they discussed Bard's complication rates.

08:48:26 THE COURT: I don't think they sat down at the

08:48:27 meeting and Bard said to the FDA we discussed complication rates. So I don't think -- her saying they discussed complication rates is conveying an assertion that was made by Bard or the FDA at the meeting for the truth of the matter 08:48:43 asserted. It's her characterization of what they said, but I don't think it's the hearsay that went back and forth between them, which I think is what you're saying is the problem.

MR. JOHNSON: Well, I still think that the subject matter that was discussed is hearsay. It's being admitted for 08:48:58 the truth of saying Bard came to the FDA and we discussed this information relating to our filter. And I do think that's hearsay.

THE COURT: Mr. North?

MR. NORTH: First of all, I don't think it is hearsay 08:49:16 because it's not the truth of the matter asserted. It's not an assertion. It is the fact that a conversation occurred.

Secondly, even if it was hearsay -- or let's say the underlying document that reflects that conversation may be hearsay. But she, as an FDA expert, this particular witness, 08:49:36 is entitled to rely upon that hearsay if it's the sort of information she typically would do so in her area of expertise.

So I think even if it was hearsay, and I don't think the statement demonstratively is, that does not prohibit it, 08:49:52 in our view, for being the basis of her opinion.

08:49:56 THE COURT: Did you want to make another point, Mr. Johnson?

MR. JOHNSON: No, sir.

THE COURT: Are there other portions of the 08:50:01 PowerPoint that you object to besides the hearsay one?

MR. JOHNSON: There are.

THE COURT: Would you tell me what those are.

MR. JOHNSON: And I don't know if I've got mine in the correct order or not. Risk-based classification medical 08:50:20 devices and with a Class II device, which is what the IVC filter is --

THE COURT: Let me find it.

Okay. I've got it.

MR. NORTH: It's 7929, Your Honor.

08:50:34 THE COURT: There's no numbers on this. But I've got -- I've got Class II.

MR. JOHNSON: Okay. The idea that they want to clump with this IVC filter contact lenses, glucose monitors, sutures.

08:50:50 This is a case about IVC filters. I think she can talk about the fact that this is a Class II device, what a Class II device is. But to somehow confuse the matter and associate it with other unrelated devices I think is a 403 issue and should not be shown to this jury.

08:51:09 THE COURT: So if she were asked during her

testimony, give the jury some examples of Class II advice -- devices, you would object?

MR. JOHNSON: I would.

THE COURT: And what's the reason for objecting if she's going to say here are five Class II devices?

MR. JOHNSON: It's, again, a 403 issue. The inference is, the confusion to the jury is that this is a low-risk device and it's no different than a contact lens, it's no different than a glucose monitor.

THE COURT: I take it you're not disputing those are Class II devices?

MR. JOHNSON: I'm not. But they all carry different risks.

THE COURT: All right.

I'm going to have to make question-by-question judgments. But it seems to me the proper way to handle that is for you to cross-examine her and say are you asserting that a glucose monitor presents the same risks as a blood filter? I've got to think she's going to say no, I'm not. And then you could just bring out the fact that Class II devices have different risks.

MR. JOHNSON: I understand, Judge. Part of my problem is, as you know, we're on a short fuse right now. We're on the clock and I'm trying to get to the point.

THE COURT: I understand that. I absolutely

08:52:36 understand that. But you've also made the decision to consume 24 hours of your time.

All right. I want to make sure I understand all of them. Are there other concerns you have about the PowerPoint?

08:52:51 MR. JOHNSON: Yes, sir. There is a slide entitled "Substantial Equivalence."

THE COURT: I'm not seeing a slide called "Substantial Equivalence."

MR. NORTH: It's behind the Class II slide in that

08:53:16 same folder. It should be.

MR. JOHNSON: There are actually a couple of substantial equivalence slides, Judge.

THE COURT: Okay. I see it.

MR. JOHNSON: Just to orient you, this is the slide

08:53:35 that has a series of bullet points.

THE COURT: Yes, I see it.

MR. JOHNSON: And I'm color-blind, so I can't tell you which bullet point I'm referring to, but it says "does not raise new questions of safety and effectiveness."

08:53:52 THE COURT: That's sort of a lavender. Okay. I see it.

MR. JOHNSON: We believe that violates this Court's -- I call it *Cisson* order, but the order on Plaintiff's Motion in Limine Number 1, which prohibits anybody

08:54:05 from suggesting that the FDA has declared this device to be

08:54:11 safe and effective.

THE COURT: Is this an accurate summary of 21 U.S.C. Section 360(c)(i) -- (1)(A)? Do you know?

MR. JOHNSON: I'd have to pull that, Your Honor. But
08:54:25 the inference here is that the FDA has blessed this device as safe and effective, and that's not the evidence. That's not what this CFR stands for, and it's not what the Court's order permits the parties to do in this case.

THE COURT: 21 U.S.C. 360(c) is what it is, Jeff.

08:54:48 I think what I'm going to have to do on that one, Mr. Johnson, is hear the question.

MR. JOHNSON: Okay.

THE COURT: I have ruled that Bard cannot suggest to the jury that the FDA made a finding that this device is safe
08:55:01 and effective. And I'm going to stand by that ruling. But I think I'm going to have to hear specific questions.

If this is an accurate statement of what's in the statute, I don't think it's a problem for them to bring that out. But if you use it then to suggest that the FDA made a
08:55:18 finding of safe and effectiveness, safety and effectiveness, then I'm going to sustain the objection.

MR. JOHNSON: Okay.

THE COURT: So I think I need to wait and rule on that one.

08:55:28 MR. JOHNSON: Okay. The next slide is entitled

"EVEREST."

THE COURT: Yes. Table 19?

MR. JOHNSON: Yes, sir.

The EVEREST study is hearsay, first of all.

THE COURT: Well, let me interrupt you for a minute. What is table 19 from?

MR. NORTH: I'm sorry, I'm having --

THE COURT: It is titled "EVEREST" at the top, Mr. North, and it says "Table 19 device observations SIR standards for IVC filters."

MR. NORTH: I'm sorry, Your Honor, we are not using that one. We are not using that one.

THE COURT: Okay. Because this clearly would be hearsay. It is obviously a table from some other place.

MR. NORTH: Right.

MR. JOHNSON: And, Judge, I have to back up to Dr. Tillman's opinions. There's another bullet point I think we need to address.

THE COURT: Okay.

MR. JOHNSON: Dr. Tillman is an FDA regulatory expert. The third bullet point indicates that Bard's IFU and promotional materials include risk information that reflected current industry standards.

She is not an expert on industry standards, she's not qualified to give that opinion, and I don't believe that

08:56:47 reference is in her Rule 26 report.

THE COURT: Is that in her report, Mr. North?

MR. NORTH: It is, Your Honor. Let me find the exact point. I had it here for when we do questions.

08:57:25 87 to 88 in her report, Your Honor.

THE COURT: What does it say? Read it to me, would you.

MR. NORTH: "Dr. Parisian claims that Bard's product labeling was inadequate. Based on the materials that I have

08:57:44 reviewed, I believe that Bard's physician labeling and promotional materials were consistent with the cleared indications for use and included risk information that reflect the current industry standards at the time it was issued."

And she continues.

08:58:00 THE COURT: So it's in the report. The question, then, is a foundation question, whether she's qualified to offer that opinion.

What is the basis for her qualification to opine on current industry standards?

08:58:12 MR. NORTH: Because she is -- she spent her entire career with medical devices. First 15 to 20 years within the FDA reviewing labeling, making determinations on the adequacy of labeling, what needs to be added, what not.

She now works as an outside consultant for medical

08:58:31 device companies in helping to develop their submissions. She

has reviewed many of the competitor IFUs in this particular case for filters. I mean, she -- that's her whole career, is assessing medical devices and their labeling.

THE COURT: Mr. Johnson?

MR. JOHNSON: I think it's one thing for her to say the labeling is appropriate. Industry standards has a pretty broad, I think, implication to it. I think, again, there's a 403 argument that can be made that it's confusing and misleading. Industry standards for what, basically? If she's -- I think she can say that the labeling is appropriate, but to go beyond that, I think, is getting outside of her area of expertise.

THE COURT: Well, I think I need to hear the foundation and the question. Based on what I've heard back and forth, I can't rule that this is impermissible. I think I need to hear it in context. And you're free to make that objection, Mr. Johnson.

MR. JOHNSON: Okay.

THE COURT: Have we covered all your points?

MR. JOHNSON: Yes, sir.

THE COURT: Okay. So on the PowerPoint -- when -- on, for example, the 2004, 2005 --

Traci, would you tell the jury we're going to be just a couple of minutes.

On the 2004, 2005 regulatory history, when in the

09:00:05 questioning are you intending to put this up, Mr. North? This is the one that has all of the dates, September 17th, October 5th, et cetera.

MR. NORTH: When we begin discussing her review of the regulatory history of the Recovery filter. That will come soon after her qualifications and background.

THE COURT: Isn't that leading? If you're putting up in front of her the points you want her to cover, aren't you leading the witness?

MR. NORTH: I think I can prepare the foundation, Your Honor, in asking her did she prepare this summary to summarize the chronology, would it assist her in telling the jury her opinions.

THE COURT: All right. Here are my conclusions. I'm going to permit Bard to use the summary of Dr. Tillman's opinions, but only after she's given the summary. In other words, you can -- I would suggest you do it on the Elmo, you can move a paper down.

If I sustain an objection to one of her opinions, I'm not going to allow you to show the summary of it. But if you want to put it on the Elmo, and after she's given the first one, move it down, second, third, so you're showing them the summary, I think that's okay.

I am going to allow you to use the two regulatory history slides, if she says she prepared them, to aid the

09:02:33 jury.

I am not going to allow you to use the Class I, II, and III slides, because I think with the illustrations and the way they're portrayed, there is more of a message being sent 09:02:45 than just her testimony. I think the smiling patient in the gown on part I, the contact lens, the monitor on part II, is sending to the jury a message that I don't think she's going to send, which is this isn't a big deal, these aren't serious devices.

09:03:19 I am going to allow you to use 510(k) and substantial equivalence in the same way that you can use the summary, after she's given the testimony you can use it.

And then the EVEREST is out.

All right? Is that clear?

09:03:36 MR. NORTH: Yes.

THE COURT: Okay. And I'll rule on objections as they come.

Traci, would you give this back to Mr. North.

Defendants, is there anything pressing we need to 09:03:45 address before we bring the jury in?

MR. NORTH: The only thing I was going to bring to the Court's attention is I now understand that the plaintiffs are getting ready to rest momentarily. I did not know how quickly it would be this morning. We are going to have a 09:03:58 motion that at some point we want to bring up, and I just want

09:04:00 to be sure that I preserve that on the record in the best way not to interfere --

THE COURT: Plaintiff's counsel, you need to hear this.

09:04:06 I'm going to say you are preserving that now. Okay? So I'm not going to require them to make the motion after you rest and take the jury's time.

You're preserving it. I'll allow you to explain it at the lunch hour or the end of the day. So you don't need to

09:04:21 make -- I mean, if you want to say "I make a motion," you can. But deem it preserved now.

MR. NORTH: All right.

THE COURT: Okay.

Let's get the jury in.

09:04:31 (The jury entered the courtroom at 9:04.)

THE COURT: Good morning, ladies and gentlemen.

Have a seat, everybody.

Thank you for your patience. There were some issues we needed to work out this morning that hopefully will save

09:05:49 some time and move things along as we present evidence.

We are continuing with plaintiffs.

MR. LOPEZ: Continuing with the deposition of Dr. Rogers, Your Honor.

THE COURT: Oh, that's right. Okay, so we'll

09:06:08 continue playing the deposition of Dr. Rogers.

09:06:25 THE COURTROOM DEPUTY: It's on. It's telling me no signal.

(Video testimony played.)

MR. LOPEZ: Your Honor, at this time plaintiff rests, 09:14:27 subject to potential rebuttal.

THE COURT: All right. Thank you.

Defendants, your evidence.

MR. NORTH: Your Honor, at this time we would like to reserve the right to make a motion pursuant to Rule 50 at the 09:14:40 appropriate time.

THE COURT: All right. That's reserved.

MR. NORTH: Thank you.

At this time the defendant would call Dr. Donna-Bea Tillman to the stand, please.

09:15:16 THE COURTROOM DEPUTY: Ma'am, if you'll please come forward.

If you'll please stand right here, raise your right hand, please.

DONNA-BEA TILLMAN, PH.D,

09:15:32 called as a witness herein, after having been first duly sworn or affirmed, was examined and testified as follows:

D I R E C T E X A M I N A T I O N

BY MR. NORTH:

Q Good morning, Dr. Tillman.

09:16:02 A Good morning.

09:16:03 Q Could you tell the members of the jury where you live?
A I live in Columbia, Maryland.
Q And what is your profession?
A I'm a biomedical engineer and I do regulatory consulting.
09:16:15 Q And by whom are you presently employed?
A My company is Biologics Consulting Group.
Q And what does that company do?
A Our company is ex-FDA and ex-industry people that work with medical device and pharmaceutical companies and biologics
09:16:33 companies to help them develop the test data and the information they need to support marketing applications for FDA.
Q Dr. Tillman, have you ever testified at a trial before?
A No, I have not.
09:16:47 Q Could you tell the members of the jury about your educational background?
A Yes. So I have an undergraduate degree in engineering and biology from Tulane University. And then I went to Maryland, where I went to the Johns Hopkins University, and I got a
09:17:01 Ph.D. in biomedical engineering. While I was working for the government, I went back and got a master's in public administration.
Q And where was that master's in public administration from?
A That was from the American University in Washington, D.C.
09:17:17 Q Now, did you work for the United States government for a

09:17:19 number of years?
A Yes, I did.
Q Could you tell the members of the jury what the first agency or department of the government was that you worked
09:17:27 for?
A Yes. So I began my career in the government at the Consumer Product Safety Commission. So that is a government agency that's responsible for the safety of consumer products.
Q And how many years or what -- during what period of time
09:17:42 were you there?
A I was there from -- until 1994, I believe. For three years.
Q What was your position there?
A So my position was actually as a physiologist.
09:17:58 Q And what did you do in that role?
A So I was involved in trying to help ensure the safety of consumer products, swimming pool safety, playground safety, toys. So making sure that there were standards that ensured that those consumer products were safe.
09:18:15 Q At some point did you move agencies to the Food and Drug Administration?
A Yes, I did. So in 1997 I started my career at the FDA.
Q And what did you do at the FDA? What was your first position there?
09:18:31 A So my first position was as a reviewer in the Obstetrics

09:18:35 and Gynecology Devices branch.
Q And what did you do as a reviewer?
A So as a reviewer, I was are responsible for basically reviewing premarket submissions, 510(k)s, IDEs, PMAs. So
09:18:49 marketing applications that companies submitted for medical devices for obstetrics and gynecology devices.
Q And what branch of the FDA did you move to after your tenure with that particular area?
A So after being a reviewer in OB/GYN for three years, I got
09:19:11 the opportunity to move into a management position in a group that reviewed pacemakers and cardiac electrophysiology devices.
Q And what was your role and responsibility in that particular division or group?
09:19:24 A So as a first line manager, I had a group of about 14 reviewers and medical officers, and they would do premarket reviews. They would review 510(k)s, IDEs, and PMAs. And my job was to manage the group and to ensure the consistency and the quality of the work that came out of my branch.
09:19:45 Q Were you responsible in any way as the ultimate signatory or person to sign off on approvals or clearances of devices?
A So as a branch chief, I was able to sign off on FDA requests for additional information. So when FDA gets an application and when they review it, if there's information
09:20:05 that's not sufficient and they need more information, they can

09:20:09 send a letter to the company and say we need more information. And that's called an Additional Information Request. So I had the authority to sign off on Additional Information Requests when I was a branch chief.

09:20:21 Q I'm sorry, what was your next position with the FDA?

A So then I was the deputy director for Cardiovascular Devices.

Q And what did you do as the deputy director of that division?

09:20:32 A So then it was sort of the next level up in management. So I had several branch chiefs underneath me, and my job was to ensure, once again, consistency and quality. It was to help develop procedures within the division for managing work, and in that capacity, I did have final sign off authority on

09:20:54 510(k) submissions.

Q And what type of devices were you overseeing at that point?

A So it included the devices that I had been in the branch for, so pacemakers, cardiac electrophysiology devices, patient

09:21:08 monitoring devices, interventional cardiology devices, IVC filters.

Q And approximately how many FDA employees reported to you when you held that role?

A So the people who reported directly to me were the branch

09:21:31 chiefs. But if you include the people that reported to the

09:21:34 branch chiefs, probably 30 to 40 people.
Q And then did you move on to another position in the FDA after that with the Technology and Review Policy area?
A Yes. So then I was promoted to the next level of
09:21:50 management, which is called the office level, and I was the deputy director for Technology and Review Policy.
Q And what was your role and responsibility in that position?
A So that was a higher level position where I was working to
09:22:03 establish regulatory policies and frameworks across our premarket programs, and particularly the 510(k) review program, but also in some of our science programs.
Q And what was your next position after that with the FDA?
A So after that I actually became the director of the Office
09:22:22 of Device Evaluation.
Q And tell us what the Office of Device Evaluation is. What's the jurisdiction of that area of the FDA?
A So that's the part of the FDA that's responsible for doing the premarket reviews of all medical devices, except for what
09:22:38 we call the IVDs, or in vitro diagnostic devices. So my office was responsible for all of the premarket reviews, and my job was to ensure the quality and consistency of all of the premarket reviews coming out of my office.
Q Did you have a role in developing policy or guidance
09:22:59 documents in that particular position?

09:23:01 A Absolutely. As the office director, it was my responsibility to determine which guidance documents were needed, and then to work with the appropriate regulatory policy folks to develop and implement those guidance documents.

09:23:14 Q Can you estimate for us how many scientists and clinicians worked under your supervision in that role as the director of the ODE, Office of Device Evaluation?

A So at the time I left, I believe there were 350 folks in the office.

09:23:31 Q So how many years total did you work at the FDA, Dr. Tillman?

A So I was at the FDA for 17 years.

Q And can you estimate how many premarket submissions you were involved in for medical devices over your years at the FDA?

09:23:46 A Yeah, many, many. I would say somewhere in the 1- to 2,000 range.

Q And what about with 510(k) submissions?

09:24:03 A The vast majority of the submissions I was involved with were 510(k)s, because most devices go to market through the 510(k) pathway.

Q Am I correct that you left the FDA in April of 2010?

A That's correct.

09:24:16 Q And where did you go when you left the FDA?

09:24:20 A So medical device software has always been an area I've been interested in a lot, and that area was just starting to grow. I was approached by Microsoft, and they were standing up a medical device software program and it was a really
09:24:34 amazing opportunity to go to work for a company that was sort of a leader in the IT space, so I went to work for Microsoft.
Q So what was your position at Microsoft?
A So I was in the health solutions group, and my position was the regulatory affairs director, basically.
09:24:55 Q And why did you decide to leave Microsoft after a couple of years?
A So as part of its growing business in that area, Microsoft decided to enter in kind of a joint venture with another company and they wanted me to move to Seattle, and that just
09:25:10 wasn't going to work for me. I couldn't move my family.
Q So is that when you began work with your present company, Biologics Consulting Group?
A That's correct. I joined Biologics Consulting about six years ago.
09:25:24 Q And tell us generally what sorts of activities you do as a consultant with that group.
A So most of the work I do is to work with small companies who have novel medical device products, and help them understand what do you need to do to get a medical device on
09:25:41 the market in the U.S., what kind of data do you need to

09:25:45 collect to show that your product actually works, and then how do you navigate the FDA process.

Q Do you work with those companies in the development and strategies for preclinical testing?

09:25:57 A Absolutely. As an engineer, a lot of the work I do is to help my clients sort of understand what kind of technical data they need to develop their products.

Q Do you work with helping your clients get products cleared or approved by the FDA?

09:26:12 A Yes. I am very much involved with submitting 510(k) submissions and PMA submissions.

Q And are you involved with drafting labeling or instructions for use for medical device?

A Yes. Labeling is a big part of what FDA looks at in a

09:26:28 510(k) or PMA submission, and we spent a lot of time working to make sure that the labeling is consistent with FDA's regulations and policies and it provides appropriate information for health care providers and for consumers when the products are consumer facing.

09:26:45 Q In your role in assisting companies now with the development of new medical devices, do you have occasion to meet with the FDA?

A I meet with FDA fairly regularly. Actually, I live about 20 minutes north of FDA's campus, so I'm down there quite a

09:27:00 bit.

09:27:04 Q And do you generally communicate frequently with the FDA on behalf of your clients?
A I do.
Q Over the course of your time at the FDA, did you have any
09:27:17 experience with IVC filters?
A I did. I was involved in some of the early filters and the early -- the early procedures to get the permanent filters, the retrievable indications, so yes.
Q And what time period was that?
09:27:39 A I would say that was roughly in the 2004 to 2005 to '6 time frame.
Q Over the course of your career, have you given a number of professional presentations regarding FDA regulation in medical devices?
09:27:58 A Yes, I have. In fact, the Regulatory Affairs Professional Society, which oversees the regulatory affairs professionals in this country, has asked me on numerous occasions to give 510(k) workshops, and I'm actually going to Dublin, Ireland next month to do a two-day 510(k) workshop.
09:28:19 Q You mentioned that you have looked at hundreds, if not thousands, of medical devices submissions. Just give us a small sampling of the types of devices that you have worked with over the course of your career.
A So when I started in OB/GYN, I was looking at women's
09:28:36 health products. A lot of those were devices intended for

09:28:38 women's health surgery, consumer women's health products. In cardiovascular, I was very much involved with cardiac pacemaker devices, so those are permanent implants. Cardiac ablation catheters for treating arrhythmias. I do an awful
09:28:54 lot of work then and now in the cardiac monitoring space. So if you go in a hospital and you get hooked up to all those monitoring machines, I'm very much still involved in those.

And then most recently, I've spent a lot of time working on trying to understand what the regulations are for
09:29:08 mobile medical apps that might meet the definition of a medical device. So when does your phone become a medical device.

Q Can you give the jury an idea of what percentage of your professional work right now involves consulting with companies
09:29:26 in the development of medical devices?

A So the vast majority of my work is doing what I would call regulatory consulting. Probably 85 percent of it.

Q Do you also on occasion consult with companies involved in litigation?

09:29:38 A And that's probably the other 15 percent of what I do, yes.

Q And do you charge -- what rate do you charge for your litigation consulting?

A So I'm an employee of a company, so I don't actually bill
09:29:51 my clients directly. My company bills my clients for my time.

09:29:56 And so for litigation work, my company bills $500 an hour for my time.

Q Dr. Tillman, at our request, the request of myself and my team, have you had an opportunity to review the regulatory

09:30:12 history of Bard's IVC filter devices?

A Yes, I have reviewed that information in great detail.

Q Tell the members of the jury what sorts of information you have had access to and been able to review.

A So the first sorts of information I was very much

09:30:31 interested in was Bard's regulatory submissions to the 510(k) -- to the FDA. The actual 510(k) submissions.

I've also reviewed Bard's communications with the FDA. So those were the letters that FDA wrote to Bard, Bard's answers back. Meetings that occurred. I've reviewed Bard's

09:30:51 internal documents. So Bard may have submitted some information to the FDA. I would review the test reports that were associated with that. I reviewed minutes and information regarding internal Bard meetings when they were trying to investigate what was happening with some of their devices in

09:31:07 the post market setting and when they were meeting to discuss that and the test reports associated with that.

I've also reviewed relevant FDA guidances and policies that are relevant to this matter. And I've also reviewed reports from other experts, and depositions.

09:31:26 Q Have you had the opportunity to review some internal FDA

09:31:30 documents regarding IVC filters or Bard's filters?
A Yes, I have.
Q And how were you able to obtain access to internal FDA documents regarding the devices?
09:31:41 A So there's an act called the Freedom of Information Act which enables anybody who wants to request the government to provide documents that are relevant to making decisions. And so my client submitted a Freedom of Information Act to FDA, and FDA then provided the internal documents that we were able
09:32:01 to review.
Q And what sort of internal FDA documents were you able to review that had been obtained through the Freedom of Information Act?
A So those were the review memos that documented FDA's
09:32:13 findings during the review. So when FDA reviews a submission, they don't just review it and then just sort of stamp yes or no, the FDA reviewers write review memos where they document this is what I've reviewed, these are the questions that I've asked, and these are my conclusions about the adequacy of that
09:32:31 information. And so that information is collected in review memos, and those review memos are maintained in an administrative record, and that was the information that I obtained.
Q As a course of your investigation, or through the course
09:32:47 of your investigation and review of these various materials,

09:32:51 have you reached an opinion, as a regulatory professional, regarding the FDA's treatment of IVC filters?

A I believe that FDA's current regulations and approach to IVC filters, which is that they are subject to Class II and require a 510(k), is appropriate, and that it is based on the risk information that was provided. And that it is sufficient to ensure that there is a reasonable -- that the risks outweigh the benefits. The benefits outweigh the risks.

Q Have you reached any opinion as to Bard's premarket submissions?

Well, first of all, have you read Bard's premarket submissions regarding the G2 filter that is at issue in this case?

A I have. Yes. I have read them in detail.

Q And have you reached any opinions with regard to that filter? I mean those submissions, I'm sorry.

A So, yes. I believe the information that Bard provided was consistent with FDA's expectations for what should be in a regulatory submission. And I believe that the information provided was sufficient to demonstrate that the devices were substantially equivalent to the predicate devices.

Q As part of your work and review of all of these materials, have you reached an opinion regarding Bard's instructions for use? The IFU with the G2 filter and any promotional materials?

09:34:21 A Yes. I believe that the labeling that Bard provided for the G2, the instructions for use, was consistent with FDA's regulatory policy, and was consistent with what was expected for an IVC filter, and that it was sufficient to provide risk
09:34:38 information based on FDA's expectations for medical device labeling.

Q And as a part of your work and review of all of these materials, have you reached an opinion as to whether it would be appropriate for a medical device manufacturer like Bard to
09:34:54 include comparative complication data in an instructions for use?

A Yes. So in particular there's a database that FDA maintains with adverse event information called the MAUDE database. And I do not believe that it would be appropriate
09:35:12 to include comparative information based on the MAUDE database in a company's labeling.

MR. NORTH: Could you pull up 7930, please.

BY MR. NORTH:

Q Dr. Tillman, did you prepare a summary of your opinions
09:35:38 that you've just articulated for us?

A Yes, I did.

Q And is this demonstrative Exhibit 7930 an accurate summary of those opinions you've developed and just stated for us?

A Yes, it is.

09:35:53 MR. NORTH: Your Honor, if we could display this as a

09:35:56 demonstrative Exhibit 7930.

MR. JOHNSON: Your Honor, she has not expressed an opinion on bullet point number 1. I think it would be inappropriate to show this witness bullet point number 1.

09:36:07 THE COURT: Sustained. I think you haven't addressed Number 1 yet.

BY MR. NORTH:

Q Let me ask you a question this, Dr. Tillman: As a part of your assessments as to the FDA's handling of IVC filters, did

09:36:18 you take into account or reach any opinions about the agency's reclassification of that device?

A Yes, I did. I looked at FDA's reclassification information, and I believe that as part of that, FDA established what are called special controls. So these are

09:36:38 tests and guidance documents that explain what kind of information a company needs to collect in order to demonstrate that the benefits of a device outweigh the risks. And I believe that the special controls that FDA developed were appropriate, and that if they were followed, if a company

09:36:55 followed those special controls, it should mitigate the risks of the device such that the benefits outweigh the risks.

MR. NORTH: Your Honor, again, we would ask that it be displayed with that clarification.

MR. JOHNSON: No objection.

09:37:09 THE COURT: You may.

09:37:10 BY MR. NORTH:
Q Now the jury can see the demonstrative summary you've prepared. Is that an accurate summary of your opinions in this case?
09:37:23 A Yes, it is.
MR. NORTH: You can take it down.
BY MR. NORTH:
Q Dr. Tillman, let's talk a little bit about the regulatory process. And the jury has heard a lot about 510(k) and PMA and things of that nature.
09:37:38 Are medical devices categorized by the FDA into various classifications?
A Yes, they are. FDA classifies devices into three different classes based on risk.
09:37:55 Q How are those classes or categories labeled?
A So the lowest risk are Class I devices. More moderate risk devices are Class II, and the highest risk devices are classified into Class III.
Q What sort of devices are generally characterized as
09:38:13 Class III?
A So Class III are the most novel devices that present potentially the greatest risks and where they -- there may be the least amount of information known.
So earlier I talked about cardiac pacemakers. Those
09:38:27 are Class III devices. If anybody has an intraocular lens for

09:38:32 cataracts, those are Class III devices. Heart valves are Class III devices. And those are some common examples.

Q And how do Class III devices make it onto the market?

A So FDA has a regulatory process called the PMA, Premarket 09:38:47 Approval Process for Class III devices. And as part of that, a company has to show that there is a reasonable assurance of safety and effectiveness. And that generally involves bench testing, sometimes animal testing, and almost always clinical testing.

09:39:09 Q Tell us about Class II products. What sorts of products fall in the Class II category?

A So Class II devices include IVC filters, the device we're talking about here today. They include a lot of that cardiac monitoring devices I was talking about, like ECG devices or 09:39:28 pulse oximeters, if anybody's ever been in the hospital. A lot of radiology devices, like an MRI device or an ultrasound device, those are Class II devices. Hypodermic needles and syringes are Class II devices. So these devices are many of the devices you would see if you go into your doctor's office 09:39:48 and hospital.

Q And then Class I, the lowest classification you mentioned, what sort of devices are those?

A So Class I devices are the lowest risk devices. Toothbrushes are Class I devices. Surgical gowns are Class I 09:40:04 devices. A lot of manual surgical stainless steel instruments

09:40:10 are Class I devices. And Class I devices, unlike Class II or III devices, they don't require a company to submit anything to FDA to get them to go to market. So there is no premarket submission process for Class I devices.

09:40:26 Q So I believe you told us that IVC filters fall into Class II. How do Class II devices make it to market?

A So if you have a Class II device that requires -- is going on the market -- and I'm going to oversimplify a little bit, but the vast majority of Class II devices require submission

09:40:49 of something called a 510(k) Premarket Notification. There are a small handful of Class II devices that don't require any premarket review.

MR. NORTH: Could we put up 7929, what is a 510(k), please.

09:41:08 No. Several pages down. Back. Back. There.

Could we display this to the jury, Your Honor?

THE COURT: What is this --

MR. NORTH: A demonstrative --

THE COURT: We just need to identify it by number.

09:41:30 MR. NORTH: I'm sorry. 7929.

THE COURT: And this is the page on 510(k)? Just to be clear on the record.

MR. NORTH: Yes. Summary of the 510(k) process.

MR. JOHNSON: No objection.

09:41:43 THE COURT: You may.

09:41:46 BY MR. NORTH:

Q Dr. Tillman, could you tell us in more detail what a 510(k) process involves and what it requires.

A So a 510(k) is a classification process. So this is the

09:42:00 process by which FDA determines what class a device is. Is it Class I, Class II, or Class III. But in the real world, what it sends up being is a marketing application or a premarket submission.

So if you want to sell a Class II device that needs a

09:42:18 510(k), you submit this 510(k) submission to FDA and they review it. And you have to submit a 510(k) if you have a Class II device that is a new device. So if you're a medical device company and this is the first time you're selling that device, you also have to submit it if you make a significant

09:42:35 change to a device that's already gone through the 510(k) process. And when FDA gets their 510(k), they need to determine if it is substantially equivalent.

Q And explain to us what the term "substantial equivalence" means.

09:42:51 A So substantial equivalence means is done in comparison to something called a predicate device.

So if you've got a new medical device and you want to submit a 510(k), you have to identify another device that is already legally on the market, and that's your predicate

09:43:08 device. And then in this 510(k), you prepare an argument and

09:43:12 a set of data that shows that your device is substantially equivalent to that other device.

MR. NORTH: Could we show the next slide that looks like this, please.

09:43:38 Your Honor, if we could display this demonstrative Exhibit 7931 involving substantial equivalence to the jury.

THE COURT: Any objection?

MR. JOHNSON: No objection.

THE COURT: You may.

09:43:50 BY MR. NORTH:

Q Dr. Tillman, there's been a lot of discussion about substantial equivalence and when one device is substantially equivalent to a predicate device.

What is the general standard there as far as does the

09:44:07 new device have to be identical to the predicate device?

A No, it does not. In fact, the whole premise of the substantial equivalence program is to allow new devices that may not be identical to the predicate device to get onto the market.

09:44:26 Q Are there specific laws that actually define what substantial equivalence is?

A So the Food, Drug, and Cosmetic Act includes a definition of substantial equivalence. And I've prepared this slide that sort of basically summarizes it. It's a little bit

09:44:41 complicated, but I can -- would you like me to walk through

09:44:44 it?
Q Yes. Please explain what the standard is generally.
A So in order for a device to be substantially equivalent to another device, the first thing that has to happen is it has
09:44:55 to have the same intended use.
So you would identify what the intended use of the new device was, and you have to find another device that is out there that has the same intended use.
So that's the first thing.
09:45:08 And it's important to understand that a device can have slightly different indications for use but still have the same intended use.
So, for example, an IVC filter that is intended for permanent indications can be used -- has the same intended use
09:45:25 as an IVC filter for -- that can be retrieved, even though the indications are slightly different, fundamentally both devices are IVC filters that are intended to capture a clot. So that is intended use. So that's the first thing you have to show.
But the second thing you have to show is that the
09:45:43 device either has the same technological characteristics as the predicate.
So if you had a device and you were just making another device that was almost identical to that, then that would be the same technological characteristics. Or the
09:45:58 device can actually have different technological

09:46:00 characteristics.

So if you're a medical device manufacturer and you're making an IVC filter and there's another IVC on the market and your device, the design is a little bit different, that is

09:46:12 different technological characteristics.

So your device can have different technological characteristics as long as those differences do not raise new questions of safety and effectiveness, and that would be if there's some really fundamentally different design between the

09:46:28 two. And that you can actually provide data that demonstrates that your device is at least as safe and effective as the legally marketed device.

So these are -- sort of the steps that FDA walks through in determining if a device is substantially equivalent

09:46:46 to a predicate device.

Q Under the standard, does a new device have to have an identical safety profile as the previous or predicate device?

A No, it does not. The device can have different -- a different risk benefit profile as long as the overall risk

09:47:05 benefit is the same.

Q Have you seen instances where the FDA would clear a new device even though it might have more of certain types of complications than a predicate device?

MR. JOHNSON: Objection, Your Honor. Foundation and

09:47:25 403.

09:47:26

THE COURT: Overruled.

THE WITNESS: So, yes, I have. When companies develop new devices, they may often have new characteristics that might raise additional risks, but those risks may also be

09:47:40

associated with additional benefits. So their -- FDA looks at both risks and benefits. And if your device offers increased benefits, then FDA may be willing to accept more risk or more uncertainty around that device.

BY MR. NORTH:

09:48:01

Q Does -- explain to the jury what an FDA guidance is.

A So the regulatory process is a complicated one. And so FDA issues guidance documents, much the same way the IRS issues tax guidance documents, that is intended to help companies understand its policies and what it needs to do. So

09:48:25

these documents are FDA's recommendation about how companies can appropriately comply with its laws and regulations.

MR. NORTH: If we could show 7758, please.

BY MR. NORTH:

Q Has the FDA issued a guidance document to industry

09:48:46

regarding the evaluation of substantial equivalence in premarket notifications?

A Yes, they have.

Q And on your screen right now is a copy or a -- the first page of that document?

09:49:02

A That is correct.

09:49:05 Q And are you familiar with that document in your work?
A I'm very familiar with this document.
MR. NORTH: Your Honor, at this time we would introduce into evidence or tender for evidence Exhibit 7758.
09:49:18 MR. JOHNSON: Judge, this is a hearsay document, plus it's a 2014 document, it doesn't apply to this case.
THE COURT: What is your response on hearsay, Mr. North?
MR. NORTH: The response is 803(6). It is a public
09:49:29 record, Your Honor.
THE COURT: I assume you mean 803(8).
MR. NORTH: I'm sorry, 803(6), I believe.
THE COURT: 803(6) is a business record. You mean --
MR. NORTH: 80 --
09:49:43 THE COURT: 803(8) is public record.
MR. NORTH: 803(8), I believe. I think there are a number of Ninth Circuit precedents on that. Things of this nature.
THE COURT: I think we ought to talk about this for a
09:50:19 minute. Counsel, would you approach.
Ladies and gentlemen, if you want to stand up, feel free.
(Bench conference as follows:)
THE COURT: So here's my question, Mr. North. 803(8)
09:50:34 applies if it's a record of a public office, which I think

09:50:36 this is, but if it sets out the office's activities or a matter observed while under a legal duty to report, such as a finding by a public agency, or the results of a legally authorized investigation. How is this guidance document
09:50:59 describing FDA activities or a matter observed by FDA or a legally authorized investigation?

MR. NORTH: I think it's summarizing its activities in evaluating 510(k) devices, the criteria it has developed in using. It's reflecting the entire process the agency uses.

09:51:20 And I would note, too, that there are, as recently as last year, the Northern District of California, in one case, said courts routinely take judicial notice of FDA guidance documents particularly appearing on the FDA's public website.

THE COURT: Well, judicial notice is a different rule
09:51:37 than 803(8). Judicial notice is Rule 202, not -- I think it's 202. 201. Not 803(8).

And the Ninth Circuit has held that judicial notice does not permit the introduction of hearsay.

So I guess I'm --

09:52:00 MR. NORTH: Back to square --

THE COURT: I think we're back to 803(8).

MR. NORTH: I still believe we submit that in the guidance document as to how to evaluate 510(k) submissions. It's talking about the processes, its normal operations, how
09:52:16 the agency functions. It would be a classic public record

09:52:21 reflecting those activities.

THE COURT: All right.

What do you think, Mr. Johnson?

MR. JOHNSON: Judge, I don't think it covers the
09:52:27 criteria under 803(8). I'm just trying to find it exactly.

THE COURT: It is 803(8)(a)(1), (2), and (3) that I'm talking about.

MR. JOHNSON: I don't know that it sets forth the office's activities, a matter observed calling for a legal
09:52:45 duty to report. This is not a civil action against the government. I don't think the criteria is satisfied here.

THE COURT: Are you going to be introducing other guidance documents?

MR. NORTH: Yes.

09:52:58 THE COURT: How many?

MR. NORTH: Probably three.

THE COURT: What are the other two?

MR. NORTH: One is the guidance document for IVC filters, and the third one is similar to this, general policy
09:53:11 document.

THE COURT: Okay.

MR. JOHNSON: I might add this is a 2014 document. Our device was cleared in 2005.

THE COURT: What's your response on that point?

09:53:21 MR. NORTH: Response to that is I think she will

09:53:23 establish that the criteria is not changed. This is just a publication that reflects how the agency performs its duties consistently.

THE COURT: All right. I think that testimony would
09:53:33 overcome the 2014 publication problem. But I don't know whether or not a guidance document falls under 803(8). I'd like to see how the courts have ruled.

MR. NORTH: If I could just throw one other thing. The Ninth Circuit -- well, not Ninth Circuit, but there are a
09:53:48 number of cases that have made it clear that foundational testimony is not necessary under the public record exemption.

THE COURT: Right. And I think the foundation has been laid. She's identified it, it's authenticated as a government document. The question is whether it satisfies
09:54:07 803(8).

Jeff. Jeff.

I'm not going to admit it at this point. I want to look at the case law.

Jeff, would you look at the case -- look at
09:54:13 Weinstein's on 803(8). And the question I've got is whether a guidance document like this one satisfies the criteria in 803(8)(A) as setting forth the office's activities or a matter observed in the course of the office's conduct. I'm pretty sure Weinstein's will have a good discussion on that.

09:54:35 And it is on Lexis, it's not on Westlaw. You know

09:54:38 that.

I'll look at this authority that he finds over the break.

MR. NORTH: May I ask her questions now under 703 as
09:54:45 far as she can rely on hearsay even though the document's not in evidence?

THE COURT: Well, she can testify about what FDA guidance is, but it's her own knowledge. I don't think that's a hearsay problem.

09:54:56 MR. NORTH: Okay.

(Bench conference concludes.)

THE COURT: Thank you, ladies and gentlemen.

BY MR. NORTH:

Q Dr. Tillman, when the agency, the FDA, approves a
09:55:16 Class III device with a premarket approval application, it makes an affirmative finding of safety and effectiveness; correct?

A A reasonable assurance of safety and effectiveness, yes.

Q Now, just so the jury's clear, the agency does not make
09:55:34 that same finding of safety and effectiveness or reasonable assurances of safety and effectiveness when clearing a 510(k) device; right?

A That is correct. In that case, FDA is determining that the device is as safe and effective as the predicate device.

09:55:53 Q And is that the same thing as substantial equivalence,

09:55:56 essentially?
A Substantial equivalence is all of those steps I outlined on that earlier slide, but fundamentally, FDA is determining that the device is as safe and effective as the predicate.
09:56:18 Q What sort of data do manufacturers generally submit or does FDA require to show that a new device is substantially equivalent to a predicate device?
A So FDA first requires the company to compare the indications for use to the predicate to determine that it has
09:56:36 the same intended use. And then the types of data really depends on the type of device. Most 510(k)s are cleared based on what we call bench testing or engineering testing, where the device is tested on a bench.
Q What about animal studies?
09:56:55 A So some 510(k) devices, IVC filters for example, require animal studies, and a small number of 510(k)s, somewhere in the realm of 5 to 10 percent, require clinical data.
Q Now, did the FDA require clinical data to clear Bard's Recovery and G2 filters as retrievable devices?
09:57:18 A Yes, they did.
Q How does the FDA generally -- well, even with 510(k) devices, does the FDA analyze the risks and benefits of those devices?
A Yes, absolutely.
09:57:38 Q And how does the FDA generally, from your experience, go

about analyzing risk/benefit?

A So FDA actually has a guidance document that talks about how it assesses risks and benefits in the context of a 510(k). So what they're looking at primarily is they're looking at the testing data that shows what the device does and how it works, and then they're considering what is known in the public domain about the potential risks, and making a determination that the potential benefits the device offers offset the known risks.

Q If a new device provides a substantial new or unique benefit over the old device, could that be a factor in the FDA's assessment of risk benefit?

A Yes, it certainly could. Part of FDA's mission is not only to protect the public against unsafe products, but it's also to encourage innovation and to facilitate innovative products getting on the market.

MR. NORTH: If we could show 7753, please.

BY MR. NORTH:

Q Could you identify what's showing on the screen as 7753.

A Yes. This is actually the guidance document that I just referred to. It's a guidance document that talks about how FDA assesses benefits and risks when it determines substantial equivalence.

Q And what is a draft guidance as opposed to a final guidance?

09:59:17 A So the way FDA issues guidance is it prepares a document that reflects what the agency's current thinking is. So what has the agency been doing. And it publishes that as a draft guidance, and it says to the world, Here's our thoughts on 09:59:31 this matter, here's what we have been doing, we'd like to be able to formalize this, and then it provides an opportunity for people to comment. And then at some point in time, FDA then finalizes that guidance document.

Q Who ultimately decides whether a predicate device is 09:59:56 appropriate to justify the clearance for a new device?

A That is FDA's decision.

Q And who decides whether a device raises different types of safety and effectiveness questions?

A That is also FDA's decision.

10:00:09 Q And who decides whether the data provided by the manufacturer provides a reasonable assurance that the new device is as safe and effective as the predicate device?

A Once again, that is the finding that FDA makes.

Q When does the FDA determine whether a device is 10:00:29 substantially equivalent to a predicate device?

A So the way the process works is if a company wants to sell a device that needs a 510(k), they prepare the submission. It goes into FDA, FDA reviews the submission. If they have questions, they often come back to the company and ask 10:00:47 questions. The company answers the questions. And sometimes

10:00:51 there may be several rounds of FDA asking questions and then the companying responding. And then at the end of that process, if FDA determines that the company has demonstrated that the product is substantially equivalent, then FDA will
10:01:05 issue a letter that basically says, We have determined the device is substantially equivalent and you may market the device.

Q And are those the types of decisions that you generally made when you were working at the FDA?

10:01:17 A Yes. I made those decisions many times.

Q Now, once FDA clears a device for sale under the 510(k) market, is the agency finished with the device? Is that the end of the agency's role?

A No. There's two major things that go on, or maybe even
10:01:36 three. One is the company is required to maintain a quality system.

The second is that the agency has a post market surveillance program, so companies are required to submit adverse events. We mentioned the MAUDE or the MDR database.
10:01:52 So FDA monitors the performance of the device while it's on the market.

And lastly, if the company makes changes to the device, the company may actually have to submit a new 510(k) to FDA to reflect those changes.

10:02:06 Q Does the FDA sometimes make inquiries of manufacturers

10:02:11 about adverse event reports that have been made?
A Yes. If a company submits an adverse event report, and FDA has questions about it or feels it's incomplete, they will write a letter back to the company and ask for more
10:02:25 information about that adverse event report.
Q And in the course of the materials you reviewed in this case, did you see examples or instances where the FDA made inquiry of Bard regarding adverse event reports regarding -- with regard to the IVC filters?
10:02:41 A Yes, I did.
Q Now, what is down classification?
A So IVC filters were actually originally Class III devices. They didn't start out as Class II devices. And in the 1990s, FDA determined, based on some feedback from the industry, that
10:03:05 IVC filters might be appropriately down-classified from Class III into Class II. And so down classification is the process whereby FDA determines that a product can be appropriately regulated with a lower level of class.
Q So what sort of factors are important to the FDA in making
10:03:29 a determination as to whether a device can be down-classified?
A So the first thing is the risks. FDA has to feel that it understands what the risks are. FDA has to understand how often are those risks occurring. And then once we know what the risks are, FDA has to then determine can those risks be
10:03:52 mitigated? What kinds of controls can we put in place to make

10:03:57 sure that those risks are appropriately controlled so that the device can continue to perform acceptably?

So FDA has to have that information before it can down-classify a device.

10:04:12 Q Since -- I believe you just told us filters had been down-classified at some point in the 1990s. Does that mean that some of the original inferior vena cava filters on the market went through the entire premarket approval, PMA process?

10:04:29 A So as far as I'm aware of, there was actually only one filter that a PMA application, and that filter had a very novel design. And so FDA determined that it was not substantially equivalent.

The other filters, even when they were Class III devices, they were called pre-amendment Class III devices, and 10:04:47 they still went through the 510(k) pathway, but all of the filters, with the exception of this one bird's nest filter, have gone 510(k).

Q Now, as a part of your investigation and review of the 10:05:14 regulatory history of IVC filters, did you have the opportunity to review the FDA's internal discussions regarding the down-classification of filters as a class?

A Yes. When FDA was considering down-classifying filters, they prepared a memo. And in that memo they documented what 10:05:35 they knew about the risks of filters, including what were the

10:05:39 known adverse events, things like migration --

MR. JOHNSON: Your Honor, hearsay.

THE COURT: I think that's sustained with respect to what's in the communication.

10:05:53 MR. JOHNSON: Ask the Court to strike that testimony from the record.

THE COURT: The jury should disregard that answer.

MR. NORTH: Well, let's put up, if we can, Exhibit 5877.

10:06:03 BY MR. NORTH:

Q Is this the memo that you referenced?

A Yes, it is.

MR. NORTH: Your Honor, at this time I would tender 5877.

10:06:20 MR. JOHNSON: Hearsay.

THE COURT: Your response, Mr. North?

MR. NORTH: My response, again, Your Honor, is 803(6). It is a business record of the agency. 803(8), a public record. And a recent case called *McClellan* addressing

10:06:35 the same sort of requests.

THE COURT: Hold on just a minute, please.

I think you need to provide more foundation on the circumstances under which this report was created and how it became public to find out if it satisfies 803(8)(A).

BY MR. NORTH:

Q At the agency, when a memo like this is prepared, what is the deliberative process that's going on? What's the sort of procedure to reach this determination on down-classification?

A So a down-classification would involve a review team being put together that would include statisticians, clinicians, and engineers, most likely. They would evaluate the information that was in the public domain and that was provided.

This particular down-classification, there was actually two of the --

MR. JOHNSON: Excuse me, Your Honor. I'd ask that this document be taken down so the witness can't testify from it.

THE COURT: That's fine.

Let's go ahead and take it down. She can testify from her memory.

THE WITNESS: Yeah.

So FDA put together a review team.

The other thing that went into this review memo was two companies actually requested that FDA consider down-classification, and the other thing that happened was FDA had issued something called a 515(I), where they actually requested information where they were trying to decide should we keep IVC filters in Class III or should we down-classify them into Class II.

10:08:26 And so there was a public docket that gets opened, and companies and other interested parties can provide information that FDA then considers in trying to decide whether it can down-classify.

10:08:37 So all of that information that comes in through these different public processes is considered by this review team, and then that review team's findings are then documented in a review memo, and that's what that review memo is.

BY MR. NORTH:

10:08:51 Q And have you reviewed other material that talked about this and that educated you about the process that the FDA underwent with regard to analyzing the down-classification of filters?

A Yes. And I was actually at the agency when this was going

10:09:05 on. I wasn't personally involved with it, but I have been involved with other down-classification efforts, so I'm very familiar with the process.

Q And are you -- how did you obtain access to this particular memo?

10:09:18 A I believe it was provided as part of either a Freedom -- it was a Freedom of Information request that was made of the agency, and the agency provided it through Freedom of Information.

MR. NORTH: Your Honor, again, I would again tender

10:09:32 the exhibit.

10:09:34 MR. JOHNSON: Hearsay and 602, Your Honor.

THE COURT: All right. I'm going to overrule the objection and admit 5877 under rule 803(a)(1), and overrule the 602 objection.

10:09:46 MR. NORTH: Thank you, Your Honor.

(Exhibit 5877 admitted.)

BY MR. NORTH:

Q What is the concept of a special control?

A So when FDA down-classifies devices into Class II, they 10:10:11 establish special controls, and these are the activities that a company would do. They could include labeling, they can include testing, they can include other activities to mitigate the risks.

So we have a set of known risks, and then we generate 10:10:27 special controls, and those are the things that FDA says that if a company does these special controls, that the risks should be mitigated to a point at which the benefits would outweigh the risks. That's what a special control is.

MR. NORTH: Now, if we could turn to page 3 of the 10:10:44 exhibit, please.

And could we publish this to the jury, Your Honor?

THE COURT: Yes.

BY MR. NORTH:

Q On the top, the first full paragraph beginning "On the 10:11:07 basis," did the agency announce its conclusion regarding

down-classification here?

A Yes, it does -- did.

Q And what essentially did the agency determine?

A So they determined that for a specific set of indications for use that are listed on this slide, that the use of filters does not present a potential unreasonable risk of illness and injury, and that special controls will provide a reasonable assurance of safety and effectiveness.

And then they created a guidance document and standard labeling to serve as special controls.

MR. NORTH: Now, turn back to the preceding page, 002.

BY MR. NORTH:

Q Towards the bottom of the page, does the FDA acknowledge that there are risks associated with IVC filters?

A Yes, they do. And this document goes through and lays out what the risks to health are. And they're summarized in this paragraph, so they include --

MR. NORTH: Go to the top of the next page where that continues.

BY MR. NORTH:

Q And when the FDA was down-classifying filters from Class III to Class II in the 1990s, did the agency specifically acknowledge that migration, tilting, filter embolization, and fracture were known risks?

10:12:40 A Yes, they did.
Q And did the agency even recognize that those risks could be life-threatening?
A Yes, they did.
10:12:47 Q And was there any indication as to why the FDA was willing to down-classify filters even though they might have life-threatening risks?
A Yes. If you look at the last sentence here, I think FDA is recognizing that the disease itself is potentially
10:13:04 life-threatening. So recurrent pulmonary embolism can be a life-threatening disease, therefore we are -- the agency, I believe, is potentially willing to accept these risks to mitigate -- to be able to treat that disease.
MR. NORTH: If we could turn to page 5, please.
10:13:25 BY MR. NORTH:
Q At the beginning -- bottom -- well, did the FDA in the down-classification memo discuss the incidence of specific types of complications?
A Yes. In this memo, FDA basically listed out each of the
10:13:44 known potential complications associated with IVC filters, and then they provided a summary of what information they found in the published literature about what they -- what the risks were and what the potential rates at which these risks were believed to occur.
10:14:02 Q So at the bottom of page 5, it talks about filter

migration; correct?
A That was one of the risks that the agency identified.
Q And then going over to page 6.
A There are other risks, including caval penetration, filter tilting, caval occlusion.
Q Does the agency talk here about rates reported in the literature of migration?
A Yes. If you look at the top of page 6, you can see that FDA cites several references in the literature that the occurrence of filter migration can range from -- anywhere from 6 percent to 53 percent.
Q And did the agency recognize that many migrations, including those in the caudal direction, could be minor?
A Yes. As documented in this memo, FDA said that minor filter migration in the caudal or cephalad direction is commonly reported and does not appear to be associated with clinically significant events.
Q Let's look down, still on page 6, to caval penetration.

In down-classifying filters to Class II, what did the agency recognize was the reported risk of penetration in the literature with filters?
A FDA identified an article in the literature that suggested that penetration rates could be as much as 9 percent.
Q Let's go over to page 7. Fracture of the filter.
A FDA identified that fracture is -- the incidence of

occurrence of fracture has been reported at 2 percent. And they once again noted here that the complication is usually asymptomatic and requires no treatment.

Q So what is your opinion as to whether the agency, the FDA, had knowledge of the risks and potentially life-threatening risks associated with IVC filters when it down-classified the device to Class II?

A So I believe that this memo clearly documents that FDA was aware of the risks of IVC filters. It was aware of what the potential rates at which these risks occurred, and that it still felt that it was appropriate to down-classify the devices.

Q In this particular document, and as a part of this process, did the agency essentially conduct a risk/benefit analysis with regard to filters?

A I think that's a fair way to characterize FDA's decision to down-classify, yes.

Q And in your opinion, what was the decision as far as the risk-benefit calculus was?

A I believe that FDA determined that the risks were well-known and could be controlled by special controls, and that therefore they believed that the benefits outweigh the risks.

Q Did the agency develop a specific control for IVC filters?

A Yes. FDA developed a special control guidance document

10:17:23 for IVC filters.

MR. NORTH: If we could show 5126, please.

BY MR. NORTH:

Q Could you identify for the record what 5126 is?

10:17:44 A So this is FDA's special control guidance document for cardiovascular intravascular filters.

Q And explain what the purpose of this guidance document would be for manufacturers.

A So the purpose of a special control guidance document is

10:18:03 to identify what are the steps or the controls that a company needs to follow in order to ensure -- in order to demonstrate that the risks of the device were appropriately controlled, and that if the risks were appropriately controlled, then the risk-benefit profile would be acceptable.

10:18:25 Q And did the guidance document require or suggest that manufacturers conduct certain types of tests with regard to the development of IVC filters?

A Yes. There's information in this guidance document that talks about testing the materials, testing the mechanical

10:18:42 integrity of the devices, testing their ability to capture clots.

And I would also note that one of the things about a special control guidance document is that it's more than a recommendation. Because it's a special control, companies

10:18:57 actually have to -- are required to address the issues in the

10:19:00 guidance document. They don't have to do it in exactly the way the guidance document says, but they actually have to address each of the items in this special control guidance document, because it is a special control, not just a regular
10:19:13 guidance document.

MR. NORTH: Your Honor, I don't know how the Court wants to handle this, but we would be tendering 5126.

THE COURT: I think this will depend on the issue we talked about at sidebar, so we'll hold off on the admission of
10:19:26 that document.

MR. NORTH: All right.

BY MR. NORTH:

Q Did you see evidence in your review of Bard's files and materials that Bard had attempted to follow the guidance
10:19:40 document?

A Yes. Bard frequently referenced this guidance document, and based on the information that I've reviewed, I believe that Bard followed this document in the 510(k) submissions for the Recovery and the G2 filters that I reviewed.

10:20:09 Q As a part of your work in this case, did you review any testing?

A Yes. I reviewed the test reports that Bard included in the 510(k) submissions, and I also reviewed other test reports as well.

10:20:22 Q Did you review any internal analyses of Bard health hazard

10:20:27 evaluations, failure investigation reports, remedial action plans, documents of that nature?

A Yes, I did review those types of documents.

Q Did you review trending documents where Bard was tracking and trending reports of complications with the filters?

10:20:41 A Yes, I did.

Q Did you have complete access to whatever you wanted to review as a part of your investigation in this case?

A Yes, I did. If I -- during my review, I found a document that I didn't have, I asked counsel for it, and any document I asked for was provided.

10:21:02 Q The plaintiff in this case was implanted with a G2 filter. Did Bard submit a 510(k) application for the G2?

A Yes. Actually, Bard submitted four different 510(k) submissions for the G2.

10:21:20 Q What was the predicate device for the G2?

A The predicate was Bard's own Recovery filter.

Q Was the Recovery filter legally on the market when Bard submitted the G2 submission and identified the Recovery filter as the predicate device?

10:21:37 A Yes, it was.

Q To what extent, if at all, was Bard required under the FDA's rules to compare its G2 to any other inferior vena cava filter, other than the Recovery filter, which is identified as a predicate?

10:21:55

10:21:56 A So companies are allowed to choose as predicate devices any legally marketed device to be a predicate. Given that the purpose of the G2 filter program was to develop a filter that was an improved version of the Recovery filter, in my mind as
10:22:14 a regulatory consultant, it made perfect sense to use the Recovery as the predicate device.

Q Was there any requirement at all that the -- Bard somehow compare its G2 to the Simon Nitinol filter?

A No. There is no requirement that they do that.

10:22:30 Q Now, in your -- according to your understanding, what was the purpose for the changes being made to the Recovery filter to create the G2 filter?

A So Bard had two goals in that program. One was to improve the fracture resistance of the filter, and the second was to
10:22:50 improve migration resistance.

Q Did you see evidence that Bard and the FDA had been in communication about the post market performance of the Recovery filter at the time it submitted the application for the G2?

10:23:04 A Yes. I'm aware of numerous interactions between Bard and FDA regarding the performance of the Recovery filter, Bard's communications about the Recovery filter, and Bard's plans for the G2 filter.

Q Did you prepare a summary of the events and discussions
10:23:28 between -- between Bard and the FDA regarding the Recovery

filter?
A Yes, I did.
Q And did the -- Bard have a number of discussions with the FDA regarding the reports of migration death pertaining to the Recovery filter?
A Yes. When Bard started having reports of migrations with the Recovery --
MR. JOHNSON: No, go ahead.
THE WITNESS: -- filter, they reached out to FDA, and there were several phone calls. Bard shared some communications that they were preparing to submit to the community, a Dear Doctor letter with FDA, and asked FDA to comment on that. And then there were several phone calls and meetings between Bard and FDA on these issues.
BY MR. NORTH:
Q Did Bard approach the FDA about sending any notices out or letters and communications to doctors regarding the reports of migration?
A Yes. When Bard determined that one potential source of these migrations might be use in bariatric patients, Bard prepared some communications to send out to physicians, a Dear Doctor letter, we call it, and they shared a draft of that letter with FDA, and they asked FDA to provide feedback on that letter, which FDA did.
MR. NORTH: Could we display demonstrative 7928,

10:24:58 please.
BY MR. NORTH:
Q Is this the summary of the communications between the FDA and Bard regarding the Recovery filter performance that you
10:25:09 were just referencing?
A Yes, it is.
Q And did you prepare this?
A I did.
MR. NORTH: Your Honor, at this time we would like to
10:25:18 display 7928 to the jury.
MR. JOHNSON: Judge, we would object based on hearsay grounds.
THE COURT: All right. That objection is overruled. You may display 7928.
10:25:29 BY MR. NORTH:
Q Dr. Tillman, walk us through this as far as the FDA and Bard's interaction regarding the Recovery filter. What were the discussions in September of 2004 about with regard to a physician letter?
10:25:51 A So as I mentioned, Bard had identified some potential use scenarios for the filter that they thought physicians should know about, so they prepared a Dear Doctor letter, and they shared a draft of that letter with FDA.
In response to that, that communication, FDA asked
10:26:10 Bard to provide it with more information about the

10:26:14 complication rates that it was observing, and Bard provided that information to FDA.

Q When did that occur?

A That was in October. October 5th, it says here.

10:26:26 Q And did the complication data that Bard shared with the FDA include all reports of migration with regard to the Recovery filter that the company had received then, to your knowledge?

A To the best of my knowledge, it included all of the

10:26:40 information that Bard was aware of at the time.

Q Did the FDA respond to Bard about the physician letter?

A Yes. FDA asked Bard about the letter, and actually made some suggestions about some additional information to include in the letter.

10:26:58 Q And was that letter sent out to doctors about the migration?

A Yes, it was.

Q And then, in January, did Bard begin discussions or -- in the first of the year in 2005, did Bard begin discussions with

10:27:15 the FDA about improving the migration resistance of the Recovery filter and developing the G2?

A Yes, it did.

Q And during these discussions, did Bard continue to provide rate information to the FDA? Updated rate information?

10:27:33 A Yes, they did.

10:27:35 Q And did Bard and the FDA actually have a sit-down meeting to talk about the G2?
A Yes. They had a meeting to talk about the things that Bard had been doing about the Recovery, and to talk about
10:27:48 Bard's plans for the G2.
Q How would you characterize Bard's communications generally with the FDA during this time period with regard to the reports of migration and even death that were coming in regarding the Recovery filter?
10:28:12 A Yeah, I believe Bard was very transparent with FDA. They didn't wait for FDA to come ask them about this, they proactively reached out to FDA with this information, and they established a dialogue. I thought there was a good communication between the two, and it was a very interactive
10:28:29 process.
Q Does the evidence leave any doubt as to whether the FDA was clearly aware of the reports of migration?
MR. JOHNSON: Leading, Your Honor.
THE COURT: Sustained.
10:28:46 BY MR. NORTH:
Q Did you see evidence that the FDA was aware of all of the reports of migration?
MR. JOHNSON: Leading, Your Honor.
THE COURT: Overruled.
10:28:57 THE WITNESS: I believe I've seen FDA meeting minutes

10:29:01 that certainly indicate that FDA was aware of the rates, and so they were aware of the information that Bard was providing them.

BY MR. NORTH:

10:29:12 Q So when did Bard first begin to discuss the G2 with --

MR. NORTH: And we can take this down now.

BY MR. NORTH:

Q -- the G2 with the FDA?

A I can't tell you the exact date, but it was during these

10:29:27 discussions about what Bard was observing with the Recovery filter. Bard let FDA know they were working on developing a modified device that they hoped would show improved migration resistance.

THE COURT: We're going to break at this point,

10:29:41 Mr. North.

Ladies and gentlemen, we will break until 10:45. We'll excuse you at this time.

(Recess taken from 10:30 to 10:45. Proceedings resumed in open court with the jury present.)

10:46:41 THE COURT: Thank you. Please be seated.

You may continue, Mr. North.

MR. NORTH: If we could show 5349.

BY MR. NORTH:

Q Do you recognize 5349?

10:47:19 A Yes, I do.

10:47:20 Q And what is that document?
A This is the 510(k) submission for the G2 filter which was originally submitted under the name Recovery.
Q Tell us about that. The -- Bard originally submitted the
10:47:38 application under the name Recovery, and that changed at some point?
A Yes. What happened was Bard originally was viewing this as a modification to the legally marketed Recovery. So we had the Recovery filter. We talked about the fact that Bard made
10:47:55 changes to that filter to improve migration resistance and fracture resistance, and that created a filter we called the G2. But at the time Bard submitted it to FDA, they were viewing it simply as a modified version of the Recovery filter.
10:48:15 Q But at some point that changed; correct?
A Yes. What actually ended up happening was when FDA cleared this 510(k) for this modified device, FDA cleared it only for permanent filter indication.

So you may remember the Recovery was originally
10:48:31 cleared for permanent indications, and then Bard did some testing and got it cleared for retrievable indications. They made, then, changes to the Recovery filter to improve migration resistance and fracture, and submitted this 510(k).

FDA is going to come back to Bard and say we need
10:48:52 clinical data in order to validate those changes you made and

10:48:56 if you want to have the filter for retrievable indications. So Bard elected to, instead of -- Bard elected to get the filter cleared for just the permanent indications, and FDA said you can't call it the Recovery filter because it's not
10:49:11 retrievable anymore and it could confuse people. And so as a result of that, then, Bard renamed the filter the G2 filter.

Q So in it the March 2, 2005, submission, which has been marked and identified as 5349, what sorts of information did Bard provide the FDA?

10:49:35 A So this 510(k) submission was originally what we call a Special 510(k) submission, which is a 510(k) -- when a company modifies its own device, and if they don't make significant changes to it, they can submit a different kind of 510(k) where they just have to summarize the testing that they've
10:49:56 done.

So originally when Bard submitted this, it was a Special 510(k) and it included a summary of the bench testing, in accordance with FDA's guidance document, that described what Bard had done for the G2 filter.

10:50:13 Q And is this submission that you've reviewed typical of a Special 510(k) submission?

A Yes. The information that's in it is very consistent with a Special 510(k) submission.

MR. NORTH: Your Honor, at this time we would tender
10:50:27 Exhibit 5349.

10:50:29 MR. JOHNSON: Hearsay, Your Honor.

THE COURT: What's your response, Mr. North?

MR. NORTH: If they're going to object, we'll wait and bring it in with the next witness, Your Honor.

10:50:36 THE COURT: Okay. Objection is sustained.

BY MR. NORTH:

Q Now, was there a meeting between the FDA and Bard following the submission of this Special 510(k)?

A Yes. There were actually several meetings.

10:50:56 Q And what was the purpose of those meetings?

A So at those meetings, Bard -- FDA told Bard that they now believe that when companies made changes to filters that they needed to conduct clinical studies in order -- a clinical study in order to appropriately validate that change. So the 10:51:19 initial meetings were FDA basically explaining to Bard that they needed to do a clinical study before FDA would be willing to clear this new filter for retrievable indications.

Q Do you recall approximately how many FDA people were attending these meetings?

10:51:37 A Yeah. So there was a meeting held shortly after this was submitted, that same month, I believe, and there were approximately 11 or 12 people from FDA there. So it was a very large meeting of FDA representatives, and they talked about Bard's experience with the Recovery filter, what Bard 10:51:55 had done to improve upon that device, and then Bard's plans

10:51:59 for the G2 filter.
Q After those meetings, did Bard submit additional materials to the FDA as a part of a traditional 510(k)?
A Yes. So when Bard decided they were going to limit the
10:52:13 indications for the G2 to be just a permanent filter, FDA converted this Special 510(k) into a traditional 510(k). As a result, Bard then submitted all of the test reports that were needed in order to provide the actual test reports. Before, they just had a summary. Now FDA actually had all of the test
10:52:37 reports.
MR. NORTH: Could we show the witness Exhibit 5350.
BY MR. NORTH:
Q When did Bard submit the 510(k) for permanent indication for the G2?
10:52:59 A So they submitted the 510(k) originally as a special that we just talked about. It was converted to a traditional 510(k) in June of 2005.
Q And is Exhibit 5350 the converted regular 510(k)?
A Right. Yes. This is the additional information that Bard
10:53:24 submitted that would turn the Special 510(k) into a traditional 510(k).
Q And so did Bard submit various test reports to the FDA with this 510(k)?
A Yes, they did.
10:53:38 Q What sort of test reports were submitted?

10:53:41 A So they submitted the actual test reports that reflected the bench testing that they did for migration resistance, for fracture, and the other types of mechanical tests that they needed to support the 510(k) consistent with FDA's guidance 10:53:58 document for IVC filters.

Q What is a DV and V test?

A So DV and V test means design, verification, and validation. So if you have a device or product and you've established some specifications for it. So you say this is my 10:54:21 product and this is what it's supposed to do. Then you go off and you do the testing that actually shows your device does what you say it does. That testing is generally referred to as DV -- DV and V or DVT, or design verification testing. Different people use different versions of that.

10:54:48 Q What would the FDA, again, have done upon receiving this regular 510(k) submission in June of 2005 for the G2 filter? What would the agency then do upon receipt of this?

A So when Bard provides additional information, FDA reviews the information to determine whether it -- whether it's 10:55:10 sufficient to demonstrate substantial equivalence. So they would look at the test, they would look at their guidance document.

If they had any questions about the testing Bard had done, if they didn't agree with the testing, they would go 10:55:22 back and they would write a letter to Bard where they would

10:55:25 explain what their concerns were and ask Bard to provide additional information. That's how the 510(k) review process works.

Q Now, would the FDA generate internal discussion or
10:55:36 memoranda concerning its review of that 510(k) application?

A Yes, it would. So for any given 510(k), there is a lead reviewer. So -- and that lead reviewer is the person responsible for coordinating the review. And that reviewer would document what did I review and their findings and
10:55:58 recommendations in an actual review memo that becomes part of the administrative record. Just like the review memo we talked about that was generated as part of that down-classification process.

MR. NORTH: If we could display to the witness
10:56:14 Exhibit 6064.

BY MR. NORTH:

Q Did you have occasion to receive and review the actual reviewer memo regarding the assessment of the 510(k) application for the G2 filter?

10:56:31 A Yes. This memo was requested via the Freedom of Information process that we talked about before, and I was able to review it.

MR. NORTH: Your Honor, at this time we would tender 6064 under the same hearsay exception.

10:56:55 MR. JOHNSON: Hearsay, Your Honor.

10:56:56 THE COURT: All right. Give me just a minute to look at this document.

I have a question on this document, so, Counsel, could you approach for a minute.

10:58:34 Please stand, ladies and gentlemen, if you'd like to.

(Bench conference as follows:)

THE COURT: So, Counsel, it appears to me that this reflects the activities of the FDA within 803(8)(a)(1). However, when we get to page 3, it looks as though the letter

10:59:01 is quoting statements made to the FDA by Bard in bolded language. And if that's right, it would be hearsay within hearsay. That is, the quoted language would be hearsay within hearsay. That wouldn't be part of the FDA's findings and therefore not within 803(8).

10:59:41 MR. NORTH: I'm sorry, Your Honor, I see where it says "the sponsor provided." Where is the quotation?

THE COURT: Well, if you look at the paragraph I'm pointing to, right here on page 3, it says, "Please find a summary of the sponsor's response," the sponsor is Bard, "and

10:59:59 FDA's review of all of the information submitted below."

And it looks like question one is the question FDA asked, and the bolded language is the response that Bard gave.

MR. NORTH: I see what you're saying, Your Honor, but that is not true.

11:00:15 Then the agency in the bolded language is summarizing

11:00:19 itself what Bard had done and to satisfy its concern. Because the sponsor is Bard. So it says the sponsor provided the pathology reports as requested, then it refers to a veterinarian at the FDA provided a review of this information.
11:00:38 That's not knowledge Bard would have. That's part of the internal deliberations of the agency.

The reviewer says that no safety issues were identified in her review that requires the attention of the sponsor, i.e., Bard.

11:00:53 In other words, this is a summary of how the evidence has developed in the FDA's mind in response to the deficiency they identified.

THE COURT: Let me read a bit more.

I think that's looking correct.

11:01:22 I looked over page 4 and it looks as though, for example, in the first bolded paragraph, the last sentence where it says "I find this statement to be acceptable because it adequately captures." The next paragraph, "I discussed the sponsor's response." "I find the sponsor." I think that's
11:01:43 probably right, but I want to hear from you, Mr. Johnson, on that issue.

MR. JOHNSON: It's still a summary of hearsay. And I'm even getting ahead of you, Your Honor, but I see some quotes on page 4 of this document as well.

11:01:56 I mean, I would like an opportunity to go through it

11:01:59 and flyspeck it a little bit more, but I do think that a summary of hearsay isn't appropriate. It's different, in my mind, than concluding that, after review of information provided we deem this, for example, to be substantial
11:02:17 equivalence to the predicate device. So I think a summary of statements made by a sponsor would be hearsay still.

THE COURT: I think the quotes you're referring to are quotes from -- they're proposing to put into their labels.

No. I take that back.

11:02:41 MR. NORTH: There's one in that second bolded paragraph.

THE COURT: Second paragraph. Tell me -- yeah, that's clearly a hearsay statement.

So tell me what you're intending to do with this
11:02:51 letter now with this witness.

MR. NORTH: I want her to testify as to what the agency found important and --

THE COURT: Are you going to be --

MR. NORTH: -- risk/benefit analysis of the filter.

11:03:04 THE COURT: Are you going to want to display any of these bolded paragraphs?

MR. NORTH: I think they're the agency's analysis. I can happily delete this hearsay comment if that's --

THE COURT: Well, what I want to know is what you're
11:03:16 intending to show the jury and ask the witness about, because

11:03:19 I think Mr. Johnson ought to have an opportunity, in light of this exchange, to go through and identify other statements he thinks are hearsay within hearsay. And I just can't tell if you're going to have her go line by line or you're going to
11:03:34 have her talk about bolded language.

MR. NORTH: No, certainly not line by line. I'm sorry, Your Honor, my outline is over there. There's like three, four areas I wanted to address with her in the general sense.

11:03:46 THE COURT: You can grab it, that's okay.

MR. NORTH: On page 4, where the agency determines that the bench testing was adequate, that's actually the only part I was specifically going to --

THE COURT: Show me where that is, please.

11:04:33 MR. NORTH: Oh. I'm sorry. Page 3.

It says bench testing -- I'm sorry, I'm having a hard time --

THE COURT: There's a statement about bench testing in the last paragraph of 3.

11:05:10 MR. NORTH: Yes. That's what I'm talking about.

THE COURT: Says, "The sponsor's bench testing demonstrates." That's --

MR. NORTH: Yes. There. There's something at the bottom of page 4.

11:05:20 THE COURT: That's not hearsay. So you can show her

11:05:22 that.

And what at the bottom of page 4?

MR. NORTH: Let's just do 3.

THE COURT: Okay. So I'm going to admit the exhibit,
11:05:36 but subject to your identifying later, if you would like to, Mr. Johnson, statements that you think are hearsay within hearsay, that should be redacted.

MR. JOHNSON: Okay.

(Bench conference concludes.)

11:05:48 THE COURT: Thank you, ladies and gentlemen.

I will admit Exhibit 604, subject to what we discussed at sidebar.

THE COURTROOM DEPUTY: 6064.

THE COURT: 6064. Thank you.

09:25:03 (Exhibit 6064 admitted.)

MR. NORTH: If we could turn to page 3.

BY MR. NORTH:

Q Does this indicate, Dr. Tillman, that the agency reviewed in detail the testing submitted along with the G2?

11:06:24 A Yes. FDA talks in this memo about that there were -- they reviewed the animal testing provided and in the submission.

MR. NORTH: Your Honor, if we could display just this page and blow up the final paragraph.

THE COURT: You may.

11:06:48 THE WITNESS: Kind of hard for me to see here.

11:06:50 Ah. Thank you.

BY MR. NORTH:

Q What did the agency say about the bench testing specifically?

11:06:58 A So the FDA said the sponsor's bench testing demonstrates that the device performs as good as or better than the predicate device, and that the sponsor has not provided data which demonstrates that the device will not cause adverse reactions to the tissue when the device is permanently

11:07:18 implanted.

So FDA is basically going to then go on to ask Bard to provide additional information about how it determined that the modifications did not adversely affect the tissue.

Q And what is in vivo testing?

11:07:32 A So in vivo testing is testing that is done in a living organism. So it will be animal testing usually. Also could be clinical testing, but usually it's animal testing.

Q So did Bard submit additional testing materials to the FDA?

11:07:49 A So Bard had already submitted the results of the animal study to FDA, and in this question FDA is asking Bard to explain why the testing that Bard had provided demonstrates this device can be used as a permanent filter.

Q Let me ask you to look at Exhibit 6061.

11:08:15 Have you seen this document before?

11:08:23 A Yes, I have.

MR. NORTH: Let's go to the second page of this exhibit for the witness.

BY MR. NORTH:

11:08:29 Q Is this another internal reviewed memorandum from the FDA regarding the G2 filter?

A Yes. So this is FDA's review memo that documents it's review of the additional information that Bard provided in response to the question I just mentioned.

11:08:46 So FDA had some questions about the in vivo testing, Bard submitted some additional information, and this review memo documents what FDA thought about that additional information that Bard provided.

Q And this was likewise obtained through a FOIA request, F-O-I-A?

11:09:06 A Yes, it was.

Q And is this the sort of memorandum you're accustomed to seeing inside the FDA when staff members are assessing 510(k) or PMA applications?

11:09:19 A Yes. This is a common memo, and I've written many memos like this myself when I was at the FDA.

MR. NORTH: Your Honor, at this time we would tender 6061 for admission.

MR. JOHNSON: Judge, subject to redacting hearsay

11:09:33 within hearsay.

11:09:35 THE COURT: All right. So same ruling on this. The document is admissible under 803(8), but the plaintiff will have an opportunity to identify hearsay within the hearsay that we'll deal with later.

11:09:50 So I'm admitting it with that proviso.

(Exhibit 6061 admitted.)

BY MR. NORTH:

Q Looking at page 2 of this memo, it would be page 3 of the exhibit, did the agency carefully look at the response Bard

11:10:16 had submitted with regard to the animal study?

A Yes. It says in this memo that FDA had one of its veterinarians, Dr. Tory Hampshire, look at the rationale that was provided regarding the animal study, and it says that "Bard submitted an appropriate rationale for why the study

11:10:39 conducted and previously reviewed," this is the animal study, "is applicable to the filter when indicated for a permanent indication. The FDA concludes there are no outstanding questions regarding the animal study."

Q Did the FDA, after reviewing this additional material it

11:11:01 requested from Bard, go ahead to clear the device?

A Yes, they did.

MR. NORTH: If we could show the witness 5343.

BY MR. NORTH:

Q What is 5343, Dr. Tillman?

11:11:22 A So this is the letter that -- this is -- we call it an SE

11:11:25 letter, for substantial equivalence. So this is the letter that medical device companies all love to get from FDA because this is the letter saying that FDA has reviewed their 510(k) and determined that the device is substantially equivalent.

11:11:40 Q After receipt of this device August 29, 2005, would Bard have been entitled to market the G2?

A Yes. Bard could market the G2 for the permanent indications.

Q And was Bard permitted to market the G2 before receiving

11:11:54 this letter?

A No. Bard would not have been able to market it before receiving this letter.

MR. NORTH: Your Honor, at this time we would tender 5343.

11:12:04 THE COURT: It's already in evidence.

MR. NORTH: Oh. Okay. Thank you, Your Honor.

Could we display that for the jury, please?

THE COURT: You may.

BY MR. NORTH:

11:12:17 Q Now, the agency did not at this time clear the device for retrievability; correct?

A That is correct.

Q And what did the agency ask Bard to do with regard to retrieving the device? Or gaining clearance to retrieve it?

11:12:34 A So there's a special set of provisions that we refer to as

11:12:38 SE, substantial equivalence, with limitations that apply to this device.

So FDA, in reviewing this 510(k), determined that there was a likelihood that the device could be used off-label 11:12:51 for retrievable indications, and so they required Bard to put a precaution statement in the labeling that basically says that the safety and effectiveness of the G2 filter system for use as a retrievable or temporary filter have not been established.

11:13:10 Q In your experience, if the FDA was concerned about the G2 labeling or about the potential complications with the G2, would it have cleared the device?

A No, they would not have cleared the device.

Q Now, did the FDA essentially ask Bard or suggest to Bard 11:13:34 that the company conduct a clinical study with regard to the G2?

A Yes, they did.

Q And is that clinical study the study that was eventually known as the EVEREST study?

11:13:46 A Yes, it was.

Q What is an IDE?

A So an IDE is another regulatory program that FDA implements, and it means investigational device exemption.

So it is a program where, if you want to study a 11:14:05 medical device that has not been approved in a human subject

11:14:10 in the U.S., you have to -- and that study is what we call significant risk, you have to submit an application to FDA so they can make sure that the device is safe enough to be studied and that you are appropriately protecting the human
11:14:25 subjects. And that submission or that application is called an IDE.

MR. NORTH: If you could show the witness Exhibit 5324, please.

BY MR. NORTH:

11:14:40 Q Do you recognize what this document is?

A Yes. This is the IDE for the EVEREST study.

Q Before a manufacturer can conduct a clinical study like the EVEREST study, is it required by the agency to obtain an IDE?

11:14:58 A Yes. If the device is a significant risk device, the company has to obtain an IDE from FDA, and they also have to obtain approval from an institutional review board in order to begin to do the study.

Q What were the study end points for the EVEREST study? .

11:15:15 Well, first of all, what is a study end point?

A So when you do a study, you have a set of questions you're trying to answer. And so what we call those questions the study is designed to answer are the study end points.

And so the EVEREST study was really looking at two,
11:15:34 two main end points. One was could the G2 filter be implanted

11:15:40 and then retrieved at a later date? And the second end point was, what were the adverse events or the safety issues that might be observed during the time that the filter was implanted and that might be associated with retrieval.

11:15:57 So retrievability and safety.

Q Did the study actually require -- the study protocol require that the investigators record and catalog any reports of adverse events?

A Yes. Absolutely.

11:16:14 Q Did the FDA eventually grant full approval for the EVEREST study?

A Yes, they did.

Q Before doing so, did the FDA pose follow-up questions about the proposed protocol?

11:16:29 A Yes. It's not uncommon when a company submits an IDE for FDA to have questions. FDA has lots of questions, in my experience. And when you submit your IDE and FDA reviews it, oftentimes, and this is what happened here, you get a letter called a conditional approval letter. That letter is

11:16:50 basically FDA saying, yes, you can begin your study, but you need to answer these questions within the next 45 days.

Then the company needs to submit the answers to those questions. Once FDA is satisfied with the answers to those questions, then they issue a full approval of the IDE.

11:17:09 Q Do you recall what sort of questions the FDA had about

11:17:13 Bard's initial application for this IDE to conduct the study?
A I believe there were questions about some of the end points, but I can't recall all of the questions.
Q Once the FDA approved the IDE for the clinical study and
11:17:32 Bard began conducting the EVEREST study, did the company have obligations to report on an interim basis to the FDA?
A Yes. So as part of the IDE approval process, Bard was obligated to submit to FDA information about who the investigators were and what hospital sites were involved in
11:17:53 the study, and they also had to submit something called an annual report where they would provide information about the study progress, how many patients had been enrolled to date, what sites had they been enrolled at, had there been any protocol deviations, and what adverse events might have been
11:18:12 observed to date.
Q Have you reviewed these annual reports submitted by Bard?
A Yes, I have.
Q Did they accurately report to the FDA all complications that had been observed during the EVEREST study?
11:18:29 A I believe that the annual reports included all of the information the FDA would have expected to see. So Bard reported all of the adverse events it had observed. I can't independently verify if they were all of them, but they did provide what appears to be a complete list of adverse events.
11:18:50 Q Now, after Bard completed the EVEREST study, what did the

company do?
A So once Bard had completed the study, they submitted another 510(k) to FDA to expand indications of use for the G2 from permanent to include the retrievable indications.
MR. NORTH: If we can show the witness 5340.
BY MR. NORTH:
Q Do you recognize 5340?
A Yes.
Q And what is this document?
A So this is the traditional 510(k) Bard submitted to extend the indications for use from Recovery -- from Recovery -- for G2, to include retrievability.
Q As a part of this submission to the FDA, did the company provide a full report of the EVEREST study?
A Yes. There was a lengthy report that was over a thousand pages that included a lot of information about what was observed during this study, adverse events reported, and other information that FDA had asked to be included.
Q Do you recall what the G2 fracture rate was in the EVEREST study?
A It was low. I believe it was somewhere around between 1 and 2 percent.
Q Now, there has been some talk during the course of this trial of the SIR, the Society of Interventional Radiology. Are you familiar with that entity?

11:20:26 A Yes, I am.
Q And what is that, generally?
A SIR is like -- it's a professional society that represents the interventional radiology community. There are similar
11:20:39 professional clinical societies across all of medicine. And their responsibility, generally, is to establish practice guidelines and make recommendations for people practicing interventional radiology.
Q Have you seen some SIR publications regarding IVC filters?
11:21:00 A Yes, I'm aware of one of those publications.
Q And do some of the SIR publications concern complication -- reported complication rates in the literature regarding IVC filters?
A Yes, they do.
11:21:13 Q And in the course of your review of IVC filters and the FDA's treatment of those devices, have you seen evidence that the FDA looks to the SIR guidelines on occasion in assessing complication rates with filters?
A Yes. I have seen information in FDA review memo and FDA
11:21:35 documents where FDA has explicitly referenced the SIR guidelines.
Q Did it appear as if the FDA was using the SIR guidelines as a sort of rough benchmark in assessing whether complication rates are excessive or not?
11:21:55 MR. JOHNSON: Speculation, Your Honor.

THE COURT: Overruled.

THE WITNESS: So I believe that the SIR guidelines were certainly one of the things FDA considered when looking at complication rates.

Q Now, again, in this 510(k) submission dated October 31 of 2007, which is Exhibit 5340, Bard actually revealed again -- not revealed, but set forth in detail all the reported complications that occurred during the EVEREST study; correct?

MR. JOHNSON: Leading, Your Honor.

MR. NORTH: I'm sorry.

BY MR. NORTH:

Q Is that true?

MR. NORTH: Well, that's still leading.

THE COURT: Still leading. Objection sustained.

MR. NORTH: Sorry about that, Your Honor.

BY MR. NORTH:

Q Did the company report to the FDA the complication rates from the EVEREST study?

A Yes, they did.

MR. NORTH: If we could look at Exhibit 5339, please.

BY MR. NORTH:

Q Did the FDA clear the G2 for retrievable use?

A Yes, they did, in 2008.

Q And what was the exact date of the clearance letter?

A January 15, 2008.

11:23:11 Q And is that clearance letter set forth as Exhibit 5339?
A Yes, it is.
MR. NORTH: That may be in evidence also. I'm going to tender it if it's not.
11:23:26 THE COURT: It is not in evidence.
Your response, Mr. Johnson?
MR. JOHNSON: Judge, 402, 403. This postdates the implantation of Ms. Booker's device.
THE COURT: Overruled on 402 and 403. 5339 is
11:23:46 admitted.
(Exhibit 5339 admitted.)
MR. NORTH: Could we display this to the jury, Your Honor?
THE COURT: Yes.
11:23:53 BY MR. NORTH:
Q So Exhibit 5339 again. What is that?
A So this is FDA's SE letter to Bard that says they had determined that the G2 filter for retrievable indications was substantially equivalent.
11:24:13 Q I believe you said earlier you referenced four clearance letters related to the G2 in some fashion.
A That's correct.
MR. NORTH: Let's look at Exhibit 5354, if we could.
BY MR. NORTH:
11:24:25 Q And what is this?

11:24:33 A So this is a Special 510(k) that was submitted for the G2 while the EVEREST study was under -- under -- under way to add a new type of delivery system. There was no change to the filter itself, but there was a new method for delivering it.

11:24:52 Q And what sort of information would the company have been required to submit to the FDA in -- with respect to a Special 510(k) such as this?

A So they would have needed to submit testing -- a summary of testing information and an assessment of risks associated

11:25:09 with the new delivery system.

So they would have had to summarize how they tested the new delivery system to show that it actually met its specifications.

Q In reviewing this Special 510(k) with regard to the

11:25:23 delivery system for the G2, if the agency had any concerns at that point with the device itself, could it have raised those concerns with the company?

A Yes, they could have. It's certainly been my experience in the many years I've been doing this that if FDA has

11:25:43 concerns about a device that's already been cleared, one of the ways that it can sort of address that is when a company submits a new 510(k) for a modification to it, FDA will often use that as an opportunity to ask questions that relate to the concerns it has about the device. And that did not happen in

11:26:01 this case.

11:26:03 Q In this particular case did the FDA have any questions or concerns about the actual filter that it expressed to Bard as part of the review of this 510(k)?

A I'm not aware of any formal request for additional

11:26:17 information on this 510(k).

Q And what did the FDA do in terms of clearance with this particular device -- submission?

A So this 510(k) submission was cleared.

MR. NORTH: Could we display 5353, please.

11:26:37 BY MR. NORTH:

Q Is this a copy of a clearance letter regarding the jugular delivery system?

A Yes, it is.

MR. NORTH: At this time we would tender 5353.

11:26:53 MR. JOHNSON: No objection, Your Honor.

THE COURT: Admitted.

(Exhibit 5353 admitted.)

BY MR. NORTH:

Q And is 5353 a copy of that clearance letter?

11:26:59 A Yes, it is.

Q What was the date of that letter?

A November 25, 2005.

Q Now, was there a fourth 510(k) submitted related in some way to the G2?

11:27:14 A Yes, there was another, I believe it was a Special 510(k)

for a change to the spline system.

MR. NORTH: Could we display 5361, please.

BY MR. NORTH:

Q Is this a copy of that Special 510(k) concerning the spline system?

A Yes, it is.

Q Could you enlighten us and tell us, if you know, what a spline system is.

A So it's part of the mechanism once again that's used to deliver the filter. So it's not a change to the filter itself, it's a change to the actual delivery mechanism.

Q At the time -- do you recall when this -- what was the date of this submission?

A September 25th, 2006.

Q At that point in time, if the FDA had any concerns about the G2 filter's performance itself or about its labeling, could the FDA have done something in the context of reviewing this 510(k)?

A Yes. As I mentioned for the last 510(k), FDA would use a new device as an opportunity to ask any questions about an existing device if it had any concerns.

Q And what did the FDA do in response to this?

A So this 510(k) was also cleared without any questions.

MR. NORTH: If we could show 5362, please.

11:28:40 BY MR. NORTH:

Q Do you recognize 5362?

A Yes, I do.

Q And what is this?

11:28:51 A So this is a copy of FDA's October 26th, 2006, substantial equivalence letter for the modified G2 system.

MR. NORTH: Your Honor, at this time we tender for evidence 5362.

MR. JOHNSON: No objection.

11:29:08 THE COURT: Admitted.

(Exhibit 5362 admitted.)

MR. NORTH: Could that be displayed to the jury?

THE COURT: Yes.

MR. NORTH: Thank you, Your Honor.

11:29:15 BY MR. NORTH:

Q Is this a -- I'm sorry. Is this a copy of the clearance letter for the tight spline system?

A Yes, it is.

Q And was this issued fairly promptly after the initial

11:29:35 application?

A Yes. Appears to have been issued within 30 -- 31 days, I would say.

Q If the FDA had any concerns at that time with the G2 filter itself, or the complications that had been reported to

11:29:51 the MAUDE database, could the FDA have used this submission as

11:29:57 a vehicle to discuss those concerns with Bard?
A Yes. Absolutely.
Q And did that happen in this case?
A To the best of my knowledge, it did not.
11:30:11 Q So at any time in the review of these four separate applications involving in some fashion the G2 filter, did the FDA ever express concern to Bard regarding complications that had been reported with the device?
A So during the review of the 510(k)s, FDA had some
11:30:34 questions that it asked Bard, but those were questions about things that it had observed during the study. And Bard was able to satisfactorily answer them all.
Q During its review of all four of these 510(k) submissions, if the agency had any concern about the labeling or warnings,
11:30:55 could they have expressed those to the company?
A Yes. Absolutely. There's -- FDA frequently asked companies to make changes to labeling or warning statements or any information about a product in its labeling if it feels it doesn't -- it's not appropriate.
11:31:14 Q In your experience, would the FDA have cleared the device if it had concerns about the complications that Bard had observed during the EVEREST study and had shared with the FDA?
A No. I can say that FDA would definitely not have cleared the device.
11:31:34 Q As a part of your work in this particular case, have you

had the opportunity to review Bard's warnings to doctors with regard to the G2 that were contained in the instructions for use?

A Yes, I have reviewed Bard's instructions for use and its cautionary information.

Q Based on the information you have reviewed, how would you characterize the information provided to Bard -- by Bard to doctors in the G2 IFU?

A So I believe the information is consistent with the recommendations and FDA's guidance documents. I've also done a web search and looked at the labeling for several of Bard's competitors, and I believe that the labeling -- Bard's information and its labeling is consistent with what I've observed for its competitors. And I also believe if FDA had not been happy with the labeling, it would have asked Bard to make changes.

Q And if the FDA had wanted different wording in the Bard G2 labeling, could it have requested it?

A Absolutely.

Q Were there some occasions with regard to the G2 that the FDA did ask for labeling?

A I believe there were some instances where FDA asked for labeling changes, yes.

Q There has been some suggestion during the course of this trial that the IFU for the Bard G2 filter --

11:33:07 THE COURT: Mr. North, please direct your question to the witness.

MR. NORTH: I'm sorry.

BY MR. NORTH:

11:33:12 Q Do you have an opinion as to whether an IFU can appropriately contain data comparing complication rates among filters or devices?

A So the only time it would be appropriate for that information to be included would be if there were -- if there

11:33:31 had been a clinical study of that device, and as part of that clinical study there were two devices studied and the labeling might include results from both of those devices.

But if you're talking about adverse event data from the publicly available MAUDE database, then, no, I do not

11:33:53 believe it's appropriate to include that kind of comparative information in device labeling.

Q Why would it not be appropriate to include information regarding the MAUDE database information in there?

A So the MAUDE database, and that is the FDA's data

11:34:10 repository for required and voluntary adverse events, is subject to a number of limitations.

First of all, it's well known that the events are not always reported. So events may occur and may not be reported.

Secondly, in the MAUDE database we just have the

11:34:30 number of events. If we don't know how many devices each

company sold, it's very difficult to figure out how to compare one company having five events with another company having ten events without understanding what the denominator is.

In fact, FDA's own website for the MDR database actually has a statement on there that says that the rate information should not be directly compared from one company to the another -- to the other due to these limitations.

MR. NORTH: If we could display Exhibit 7795.

BY MR. NORTH:

Q What is 7795?

A So this is a screen shot of FDA's MAUDE database. The portal into FDA's MAUDE database.

MR. NORTH: Your Honor, at this time we would tender 7795.

MR. JOHNSON: 802.

THE COURT: Hold on just a minute, please.

Are there multiple pages to this document, Mr. North?

MR. NORTH: There's one more page.

If you could show page 2.

THE COURT: He just did.

I think this falls into the same category as the guidance documents that I'm looking at some case law on, so I want to hold off on my ruling on 802 until I've had a chance to look at this.

MR. NORTH: Okay. Thank you, Your Honor.

11:36:14 BY MR. NORTH:

Q Can the MAUDE database alone establish the rate for any complication rate for any device?

A So in order to establish rate, you have to have how many 11:36:33 events occurred and how many devices are out there. So there is no data in the MAUDE database about the number of devices that are sold. So you can't use it to get a rate.

Q Are there any sources of information on sales to figure out how many devices are out there?

11:36:56 A So there is a commercial database, the IMS database, that I'm aware of but not terribly familiar with, where that has information that it obtains from a variety of sources that purports to have information about how many of a particular device has been sold by each company. So people, not 11:37:19 uncommonly, will look to the IMS database as a way to understand how many of each device type a different company might sell.

Q Does the FDA generally permit a manufacturer to include flawed or incomplete data in its warnings?

11:37:36 A No. FDA would not allow that kind of information in a warning.

Q As a part of your work in this case, have you looked at some competitive IFUs? In other words, IFUs of other manufacturers.

11:37:56 A Yes. In order to -- in order to evaluate Bard's

11:38:00 instructions for use, I did do a web search to go look at several of the competitors' labels for devices that have been cleared by FDA.

MR. NORTH: If we could display number 7787 to the

11:38:13 witness.

BY MR. NORTH:

Q Can you tell us, Dr. Tillman, what 7787 is?

A So this is the instructions for use for the Cordis OptEase vena cava filter.

11:38:28 Q And is this one of the IFUs you reviewed?

A Yes, it is.

MR. NORTH: Your Honor, at this time I would tender this Exhibit 7787.

MR. JOHNSON: Multiple objections, Judge. 602, 401,

11:38:42 402, 802.

THE COURT: What is your response on hearsay?

MR. NORTH: It's not being offered for the truth of the matter asserted. And, also, it is relied upon by an expert under Rule 703.

11:39:01 THE COURT: Well, that's a different basis that requires more discussion.

MR. JOHNSON: Judge, I also don't believe this was in her report either.

THE WITNESS: It was.

11:39:09 THE COURT: Hold on. Hold on. That wasn't directed

at you.

Was this in the report, Mr. North?

MR. NORTH: Yes, Your Honor. On pages 84 of her report she addresses completely labeling of other manufacturers.

THE COURT: All right. I think I need to look at the document on the truth of the matter asserted issue. I'm happy to do that. I don't know if you want to move on or if you want me to do that now. If you want to do it now for your next questioning, I'll do it. I'll just have everybody stand up for a minute, but I'll need to look at it.

MR. NORTH: Okay. Can we do that now?

THE COURT: Yeah.

Ladies and gentlemen.

Mr. Johnson, if you want to --

(Bench conference as follows:)

THE COURT: You've got a copy of 7787? This is it?

MR. JOHNSON: Yes. Yes.

THE COURT: So tell me what use you're going to make of this, Mr. North.

MR. NORTH: Use is, number one, the main thing, is that there's no comparative complication data in a competitor's IFU. I have two of those to show her. It's not the custom of the industry to do this. I think custom of the industry is a relevant factor under *Banks versus ICI Americas*

11:40:42 under reasonableness of conduct and warnings.

THE COURT: Okay. So one of the things you're going to point out is there's no comparative data?

MR. NORTH: Right. That's it.

11:40:52 THE COURT: That's all? All right.

If the purpose is to just show the lack of comparative data, then do you believe, Mr. Johnson, this is being offered for the truth of the matter asserted?

MR. JOHNSON: I do. We're talking about whether or

11:41:08 not other companies actually have numbers that compare rates. So I do believe so. I'm looking at page 84 of her report and I don't see --

MR. NORTH: Let me get my notes.

THE COURT: Hold on a second, let him grab his notes.

11:41:55 MR. NORTH: First paragraph.

THE COURT: First paragraph on page 84. Does she say anything about the Cordis IFU?

MR. NORTH: Not specifically about the Cordis, just in general terms of other IFUs.

11:42:14 THE COURT: All she says is she's not aware. She didn't say she looked at Cordis and it doesn't include it?

MR. NORTH: No.

THE COURT: All right. I'm going to sustain the objection, then.

11:42:22 This is yours.

11:42:23 (Bench conference concludes.)

THE COURT: Thank you, ladies and gentlemen.

BY MR. NORTH:

Q Dr. Tillman, outside the filter context, have you seen any devices either that contain comparative data?

11:42:52 A No. I'm not aware of ever having seen comparative MAUDE or MDR data in any device labeling.

Q During the course of your work in this case, have you seen any labeling or promotional materials by Bard that, in your

11:43:12 view, inappropriately reflected risk information?

A No. I believe that Bard's labeling is consistent with what I would expect to see, given my understanding of these devices, and I think it's consistent with FDA's guidance document.

11:43:31 Q In submitting the 510(k) applications to the FDA with regard to the G2, and responding to the FDA's questions with regard to the G2, did you see any occasion that the -- Bard did not disclose information to the agency as a part of the 510(k) process?

11:43:55 A I believe that all of Bard's responses to FDA were accurate and reflected the information that Bard -- that they accurate based on the information I had available to me.

Q And does the evidence that you've reviewed give you any opinion as to whether the FDA conducted a risk/benefit

11:44:15 analysis regarding Bard's filters?

11:44:18 A I believe in determining that the device was substantially equivalent, FDA conducted a risk/benefit analysis. I think they had to look at, particularly for the retrievable indications where they had the clinical data and they had the
11:44:32 safety data, I think they looked at that information, as documented in their review memos, and they made a determination that even though there were adverse events observed during the study that the potential benefits outweighed the risks. And that if they hadn't made that
11:44:46 decision, they would not have cleared the 510(k).

MR. NORTH: Your Honor, subject to those, I believe, four documents that the Court has reserved ruling on, which, depending on the Court's ruling, I may want to address, that concludes my direct.

11:45:02 THE COURT: All right.

Cross-examination?

MR. JOHNSON: Yes, sir.

MR. NORTH: Your Honor, could I ask one more question?

11:45:14 THE COURT: Yes.

MR. NORTH: I think this is a repeat of something last week.

BY MR. NORTH:

Q Dr. Tillman, all of the opinions today, do you -- that you
11:45:21 have given to this jury, do you hold those to a reasonable

11:45:25 degree of certainty as an expert in FDA regulatory compliance and the clearance process?

THE WITNESS: Yes, I do.

MR. NORTH: Thank you.

11:45:34 THE COURT: All right.

Mr. Johnson.

C R O S S - E X A M I N A T I O N

BY MR. JOHNSON:

Q Good morning.

11:46:06 A Good morning.

Q Couple of follow-up questions. And I just want to make sure we all understand one another.

Both the Recovery filter and the G2 filter were cleared by the FDA; correct?

11:46:18 A That is correct.

Q There has never been a determination by the FDA that either the Recovery filter or the G2 filter is safe and effective. Agreed?

A I would agree with that statement, yes.

11:46:32 Q All right.

You have been talking about a lot of stuff here, and I just want to make sure I understand the technicalities in the process.

You talked about animal testing and you talked about

11:46:43 bench testing; correct?

11:46:44 A Yes, I have referred to both of those.
Q And we know that animal testing is not transferable one to one to humans. Agreed?
A Yes. I would certainly agree that there are some
11:46:58 questions that can be answered in animals but other questions that require human clinical studies.
Q All right. And we talked about bench testing. That is laboratory testing; correct?
A Yes.
11:47:09 Q And then there's the real world; correct?
A Yes.
Q And the real world consists of real people that are mothers and fathers and children, you name it; correct?
A Yes.
11:47:24 Q And the obligation of Bard continues after clearance is obtained for one of its filters. Do you agree?
A I would agree that medical device companies have post marketing obligations, yes.
Q So just because a device is cleared doesn't end Bard's
11:47:43 obligations.
A I think that's a fair statement. Yes.
Q Would you agree with me that the FDA regulations require that all information in the 510(k) application be truthful, accurate, and that no material fact be omitted?
11:48:02 A I would agree with that.

11:48:03 Q Would you agree with me that when a 510(k) application is submitted, the FDA always has to assume the information given by companies like Bard is truthful?

A I think FDA has to assume that the information is 11:48:20 truthful. Yes.

Q And if a company like Bard is not truthful in its 510(k) application or in its obligations after the device is being used in the real world, this system falls apart. You would agree?

11:48:38 A I would agree that FDA has to rely on companies providing truthful and accurate information, yes.

Q Because if they're not, real people can get hurt. Agreed?

A I would agree that is certainly a possible outcome.

Q And real people can die. Would you agree?

11:48:58 A Once again, I would agree that is a possible outcome.

Q All right.

And in this case, I want to make sure what your role is. You are not acting as an auditor or an investigator to determine whether there was something that should have been 11:49:12 submitted by Bard to the FDA that was not submitted. Agreed?

A I would agree with that.

Q And just like the FDA, your opinions today depend upon Bard being truthful with you. Agreed?

A I would agree I can only form opinions based on the 11:49:32 information I have, yes.

11:49:37 Q All right. And as it relates to your role in this case -- and, by the way, I think you told us you are the former deputy director of cardiovascular devices with FDA; correct?

A And the former director of the office of device

11:49:53 evaluation. Correct.

Q You are not giving an opinion today about the safety, the performance, the risks and benefits of Bard filters. Agreed?

A Only insofar as those factors weigh into FDA and the regulatory decision-making process.

11:50:15 MR. JOHNSON: Greg, will you please queue up page 70, lines 8 through 15, of Dr. Tillman's deposition given August 4th, 2017.

BY MR. JOHNSON:

Q Ma'am, you remember giving a deposition in this case?

11:50:32 A I do.

Q Let's see if you remember this question and this answer.

MR. LOPEZ: Do you want to publish it?

MR. JOHNSON: Please. Yes, may I publish it?

THE COURT: You may.

11:50:45 (Video clip played:)

Question: "You're not here to testify as to what a reasonable doctor would expect Bard to share with them about the performance, the safety, the risks and the benefits of their product. True?"

11:51:05 Answer: "That's true. I cannot say what a

11:51:07 reasonable doctor could or should expect Bard --"

BY MR. JOHNSON:

Q Do you remember those questions and that answer you gave?

A Yes.

11:51:17 Q All right. And you have not done a risk/benefit analysis of the Bard filters in this case; correct?

A That is correct.

Q And you would agree with me that Bard's responsibility for assuring the safety of a device throughout its lifespan is a

11:51:39 continuing obligation; correct?

A I would agree that companies have a responsibility to make sure their products continue to be safe and effective, yes.

Q All right. And you haven't been told in your role as an expert in this case, nor were you told when you were the

11:51:59 deputy director of cardiovascular devices, that 15 months before Ms. Booker was implanted with her G2 filter that Bard had determined there was an unacceptable safety risk for the G2; is that correct?

A I'm not aware of the infer- -- what you're talking about.

11:52:20 So, no, I was not aware of those -- that scenario.

Q I want to make sure we understand one another. When you were with the FDA, that information was never given to you; correct?

A I can't speak to entirely what information was given to

11:52:36 FDA and when.

11:52:38 Q And as an expert in this case, that information has not been given to you?

A I'm not sure exactly what information you're talking about.

11:52:49 Q That Bard had determined the G2 filter had an unacceptable caudal migration risk.

A That sounds like an opinion, not information. So I would have to understand what the basis of that statement was.

Q You haven't been provided with the test results regarding

11:53:07 caudal migration, have you?

A I have certainly reviewed test reports addressing caudal migration.

Q All right. And you told us that Bard, or the attorneys for Bard, provided you with that information; correct?

11:53:19 A All of the information I have in this matter was provided to me by the attorneys. Or from FDA's website.

Q And do you believe if you had been provided with a safety test result demonstrating that the G2 filter had an unacceptable caudal migration risk, as an expert in this case

11:53:38 you probably would have remembered that?

A I think you're talking about -- when you say an unacceptable risk, that is an opinion, so you'd have to be more clear about what the -- what the fact was that was observed.

11:53:53 Q Here's the question: Do you remember a Bard document

opining that the G2 filter had an unacceptable caudal migration risk?

A I'm not sure what document you're referring to.

Q Okay.

Have you been provided information by Bard that the company had determined when the G2 filter caudally migrates, that leads to tilt, leads to perforation of the IVC, the vena cava, it in turn leads to penetration of nearby organs, and it leads to fracture? Have you been provided that information?

A I'm certainly aware of the fact that when devices migrate that some of those other events can happen. I'm not sure what information you're talking about.

Q We're here to talk about the Bard filters; correct?

A Yes.

Q I want to limit our questions and answers to the Bard filters, if that's okay with you. All right?

Has Bard provided you with their information where they have concluded that caudal migration of the G2 filter leads to filter tilt, leads to penetration of the vena cava, in turn leads to penetration of adjacent vital organs, and it leads to fracture?

A Yeah, I just need you to be a little more specific about what you're talking about.

Bard provided me with a tremendous amount of information. They certainly provided me with information

about caudal migration. But I'm not sure exactly what you're -- what you're referring to. I'm sorry.

Q You don't remember seeing anything that describes the domino effect I just laid out for you?

A Sitting here today, I can't recall it. That doesn't mean I've not seen it.

Q All right. You haven't seen that same evidence having been provided by Bard to the FDA, have you?

A I'm not sure what evidence you're talking about.

Q Caudal migration leading to filter tilt, leading to perforation of the vena cava, leading to penetration of adjacent organs, leading to fracture.

A So that sounds like a series of events that can occur when there is caudal migration. So if you're asking me whether I've ever seen Bard present that as a possible scenario to FDA, I would say no.

Q Thank you.

You talked about the EVEREST study. Do you remember that?

A The EVEREST study, yes.

Q Okay. And the purpose of that study, that is the study objective, was to assess the safety of removal of the filter; correct?

A That was the overall study objective.

Q All right. And the length of this study was what?

11:56:54 A What do you mean by length? There were a bunch of time frames in the study.
Q Was it a six-month study?
A So the design of the study was that Bard would enroll up
11:57:06 to 100 subjects, and that the study would be concluded once 30 subjects had had their filter removed and been followed for, I believe it was either one month or six months. I can't recall as I sit here today.
Q This was not a long-term safety study of the Bard G2
11:57:27 filter, was it?
A No. It was not intended to look at the long-term impact of permanent implantation of the G2 filter.
Q This was a retrievability study only. Agreed?
A I wouldn't say it was retrievability only because it also
11:57:44 included an assessment of adverse events throughout the implantation period.
Q And with 100 patients over six months, there was a filter migration rate of 12.2 percent. Do you remember seeing that?
A I would -- I believe that that is the filter migration
11:58:02 rate that was observed, yes.
Q And after six months there was a filter penetration rate of 21.7 percent. Do you remember seeing that?
A Yeah. I'm not sure I agree with your "after six months," because six months from when? But I would agree that the
11:58:20 penetration rate is the one that I recall.

11:58:23 Q All right. If the EVEREST study does reflect a filter penetration rate of 21.7 percent, you would not dispute that. Agreed?

A I believe that that is what was reported in the clinical 11:58:34 study report, yes.

Q All right. And as we talked about, in the real world and real people, these problems need to be surveilled and looked at by a device manufacturer like Bard. Agreed?

A I'm not sure I understand your question as you phrased it.

11:58:53 Q Sure. There's a continuing obligation to monitor these complications.

A I'm not sure I agree with the word "monitor." I think Bard does have an obligation to report adverse event data to FDA and to manage complaints as they come in through its 11:59:08 complaint handling system.

MR. JOHNSON: Greg, would you pull up Exhibit 2052, which is in evidence, and locate page 18.

Your Honor, may I publish this to the jury?

THE COURTROOM DEPUTY: It's in.

11:59:37 THE COURT: Yes.

BY MR. JOHNSON:

Q Ma'am, have you been provided with this G2 trend table relative to the Recovery filter?

A I may have seen this during a deposition, but I don't 11:59:57 recall that this was actually part of a test report or any FDA

12:00:02 submission.
Q You're correct. It was never provided to the FDA, was it?
A But I'm not sure where these data came from. There's no footnote --
12:00:13 Q Would you like me to go to the front and we can verify this is a Bard document?
A What do you mean by it being a Bard --
THE COURT: Counsel, we're at noon. We'll break.
Ladies and gentlemen, we'll plan to resume at 1 o'clock.
12:00:28 We'll excuse the jury at this time.
(The jury exited the courtroom at 12:00.)
THE COURT: Counsel, we need copies of the guidance documents, the three guidance document exhibits, and the FDA screen shot that I need to think about on Rule 803(8). If you could just give them to Jeff. We'll look at them over the lunch hour.
MR. NORTH: I can give you another copy or if you can give me these back when you're finished.
12:01:09 THE COURT: We promise we will.
Why don't you be back at five to 1:00, and that way I can tell you my ruling on this.
(Recess taken at 12:01.)
(End of a.m. session transcript.)
12:01:27 * * * * *

C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 24th day of March, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter